Why countries need a national drug policy

Many countries still lack adequate supplies of drugs appropriate for their health needs, and the irrational use of drugs poses problems in both developed and developing countries. The reasons for this are complex and are not only the result of financial and budgetary constraints, lack of infrastructure and human resources, but also reflect the attitude and behaviour of the government, prescribers, dispensers, consumers and the drug industry. To ensure an adequate supply of safe and effective drugs of good quality at an affordable price, which are properly used, every country should have a national drug policy as an integral part of its health policy.

The ministry of health is the most appropriate department to take the lead in developing a national drug policy. However other government departments and agencies will need to participate in its development, since its success will depend on the interest and wholehearted endorsement of government officials at the highest levels. Endorsement by sectors such as planning, finance, education, legislation, industry and commerce, are of particular importance, since decisions regarding registration, import quotas, foreign exchange allocations, tariffs, marketing, and human resources development may all have significant effects on drug procurement, manufacture, distribution and use.

A policy is a guide to action and a commitment to a goal. A primary goal will be to make essential drugs available to the entire population, and to assure the safety, efficacy and quality of medicines provided to the public. The regular availability of drugs at health facilities increases attendance by increasing the credibility and acceptance of health workers, and facilitates their important role in preventive medicine. Other health related goals include improving prescribing and dispensing practice, and promoting the correct use of medicines by the public.

A national drug policy also has economic goals of which the principal will be to lower the cost of drugs to the government and the public, and to reduce the foreign exchange drain from drug imports through wiser purchasing. It will need to consider the inter-relationship between the public and the private sectors since drugs may be prescribed in the public sector but purchased in the private sector. It will also need to consider the fact that self-medication accounts for a high proportion of the drugs consumed in many countries. And finally, the policy will include national development goals, such as an improved infrastructure, increasing human resource skills in management, pharmacy and medicine, or promoting the local production of drugs.

Increasingly, countries are taking up the challenge to develop comprehensive national drug policies and in doing so, calling on the participation of the many sectors involved in this complex area. Questions which governments will need to ask include: What is the present situation? What are our needs, immediate and future? Which are our priority objectives? Where will the work be done and who will do it? How long will it take? Whom can we learn from? How much will it cost? Is external financial support needed? Who will monitor progress?

The cornerstone of a national drug policy will be legislation to ensure the safety, responsible marketing, rational selection and use of drugs entering the national market, with adequate enforcement measures to ensure that resources spent on modern pharmaceuticals are not wasted but make a positive contribution to the health of the population. Legislation should be accompanied by a plan of action for its implementation. This may have to be phased, since it will not always be possible to implement all components simultaneously.

The exercise of formulating a national drug policy provides a unique opportunity to evaluate the present, identify problems and to plan a strategy for the future involving all actors in the pharmaceutical and health field. Following this process the publication of a national drug policy explaining its rationale and implementation can be a powerful advocacy medium for its acceptance and understanding, and a valuable way to draw together the various strands of the strategy.

This issue of the Monitor includes the experience and perspectives of two African states, Malawi and Nigeria, in developing comprehensive national policies to improve the supply and use of drugs in the health care of their peoples.
Essential Drugs Monitor

RATIONAL USE

Teaching rational drug use: an experience in India


The term 'essential drugs' was first used in India by the 'Hari Committee' in connection with price control of 117 drugs used for common disorders. Today, although a definition of essential drugs is available, people have widely varying perceptions of what exactly is meant by the term.

Our early studies in the 70s on irrational drug combinations, such as penicillin V and salbutamol, amphetamine and phenacetin with aspirin, paracetamol, which sold for millions of rupees, generated much interest among the scientific community and the public. Some of these combinations were banned and others were designated prescription only drugs.

Targeting public education

At that time we found the irrational use of drugs to be widespread, and our studies made patients inquisitive about their diseases and drugs prescribed. Since there was no available published drug information for the general public, we decided to write a book providing information on commonly used drugs, including socioeconomic aspects and irrational drug combinations. The first edition was published in 1978 under the title "Medicines and their Correct Use," a name later changed to "The Complete Family Medicine Book." By 1990 the publication was in its fifth edition which shows that it meets a real need.

The introduction of the essential drugs concept by the WHO in 1977 was a major step towards overcoming the problem of irrational prescribing. We perceived it to be a very scientific concept based on sound principles of selection, procurement and rational use of drugs, and wanted to introduce these principles into our medical teaching.

Teaching better prescribing

So in 1985 we decided to test a draft curriculum on essential drugs developed by WHO. As a first step we selected medical interns since there was evidence that they were self-analyzing, receptive and free from pressure of university examinations. The program was conducted during an eight week period for 2 hours on 4 days of the week in 1986. Interns from various departments attended the introductory lectures, which were followed by discussions with a faculty member from a clinical department once a week on an appointed day. The topics covered were: the essential drugs concept, drug combinations, irrational and rational prescribing, drug interactions, drug utilization studies, and patient education in effective drug use. After about three weeks, attendance dwindled. Participants had found the course to be too theoretical and called for a more practical, oriented and interactive approach in the form of a workshop during the first two days of internship or incorporated into the undergraduate curriculum. So we had learned an early and valuable lesson. The course also helped us to identify motivated clinical faculty members.

In the following year, the programme was transformed into a practical oriented two day workshop which received very positive feedback from participants. A year later, departments conducting laboratory investigations, such as pathology, microbiology, and biochemistry, were invited to join the programme to discuss the cost effectiveness of the hospital tests. And during the last two years the radiology and forensic medicine departments have also participated to discuss the issues related to radiological investigations and medicolegal aspects.

A 'treat' for interns

The duration of the programme has increased from two to three days and it is now called "Integrated Orientation Programme for Interns." This year's feedback indicates that it should be extended to four days. So from a small activity conducted by our department, this activity has now become a regular programme of the institute to which 12 departments, namely pharmacology, surgery, medicine, pediatrics, obstetrics and gynecology, biochemistry, pathology, microbiology, radiology, forensic medicine, community medicine and medical education, contribute. Interns enjoy participating in it and call it a 'treat'.

Based on experience with the course, in 1988 we produced a manual for training interns on the essential drugs concept and rational drug use. This was subsequently modified at WHO's suggestion to focus on high morbidity areas, and to include feedback from the participants.

Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry.

National and international expansion

In order to build on and expand the success of the programme, we approached the Ministry of Health and Family Welfare to support a workshop for teachers from other institutions to train interns in this subject. The result was a three day workshop in 1989 which brought together 21 teachers from 7 medical colleges. We selected a core group of 3 participants from each college - a pharmacist and representatives of two other clinical disciplines to form a multidisciplinary team to organize similar programmes on their return. Previous training in educational sciences at the national teachers training centres was an important criterion for selection as we expected these graduates to be more motivated. Four of the participating institutions are now organizing such programmes regularly and others are planning to do so in the near future. Two other colleges are organizing programmes for prescribers and pharmacy graduates through the training imparted by us.

The training received by faculty members during meetings and courses at organizations such as National Institute of Mental Health, Washington DC; Mario Negri Institute, Milan; Karolinska Institute, Stockholm; International Organizations of Consumers Unions, Manila and Penang, and the Institute of Clinical Pharmacology, Tokyo, has greatly motivated the development of our work. Among these the multidisciplinary course on Medicine and Society: A Challenge in Health Development, organized by the Department of International Health Care Research, Karolinska Institute, Stockholm in 1987 was of particular significance. As an outcome of this, three projects, namely patients' attitude to health care, drug utilization at primary health centres, and antimicrobial utilization during cesarean section, broadened our horizon of thinking concerning the essential drugs concept. We are now planning epidemiological studies on antibiotic use and intervention studies to evaluate the long-term impact of the educational programmes.

Our activities in rational drug use continued to expand, even beyond national borders. In December 1989, participants from Nepal, Bangladesh, Pakistan, Afghanistan, Sri Lanka, Malaysia, Indonesia and India met for an international workshop on essential drugs and rational drug use in developing countries (see EDM 9.90).

As part of our continuing commitment to improving the use of drugs, a one-day workshop for 22 practitioners working in urban and rural health centres was held in 1992 to review the various components of the drug chain such as purchase, drug, disease and prescriber related factors were discussed in relation to the local cultural and socioeconomic conditions. Participants were very enthusiastic and called for a follow-up workshop of longer duration. We also provide consultancy services to various other groups involved in drug action programmes.

We believe that these activities - which range from curriculum development, the organization of workshops, publication of training materials, research and the provision of advice and information - all have a valuable role to play in the promotion of rational drug therapy and to sensitizing the many different contributors to the chain of pharmaceutical supply and demand to the issues involved.

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References

Participants at the International Workshop on the Rational Use of Drugs, Pondicherry.
APUA celebrates its first decade

This year marks the tenth anniversary of the Alliance for the Prudent Use of Antibiotics. The APUA was established in collaboration with the World Health Organization in Santo Domingo, Dominican Republic, in January, 1981, which addressed the growing problem of global antibiotic resistance, a problem which had previously only been discussed at local levels.

APUA is the only organization founded upon issues arising from a particular treatment modality, that is, antibiotics. It points out that the use of antibiotics differs from other medications in that treatment of the individual is treated society. Antibiotics not only kill the organism for which they are used but, by eliminating other susceptible bacteria, also change local ecology. A prolonged use of resistant forms of commensal bacteria lead to changes in local areas. These bacteria can transfer resistance traits to other members of the ecosystem, including human and animal pathogens.

A growing global membership

APUA membership includes researchers, veterinarians, physicians, plant pathologists, microbiologists, public health workers, nurses, dentists and other health care professionals.

Reaching out to the community

Through its newsletter and its network, APUA disseminates current information on the emergence of antibiotic resistance and on new therapies. Sections on antibiotic pharmacology emphasize the most important features of the most widely-used antibiotics. The Alliance supports symposia dealing with the resistance problem on a global scale. It has also helped to stimulate local research efforts which have examined antibiotic misuse and misuse in primary health care centers.

APUA serves the public as well. It responds to hundreds of inquiries a year about antibiotic use, side effects and resistance. The media frequently use APUA as a resource. Alliance members individually and together, have helped to disseminate information in interviews and articles which present to the scientific community and to the public a clearer picture of the problems associated with antibiotic use, misuse and resistance.

An increasing problem

What events have happened in the area of resistance since the Santo Domingo meeting? The Alliance reports that over the past ten years a new awareness in the public and in the professional world has developed about antibiotic resistance. To a large extent this awareness has increased because the problem has not gone away. The emergence of strains resistant to newer agents, at rates previously unheard of, has sparked increased concern.

Who would have predicted, it says that within the last ten years, not only did we design newer B-lactams to circumvent resistant mechanisms, but bacteria emerged to degrade these new drugs. Some new B-lactams appeared less than a year after introduction of the new B-lactam antibiotic. Why so fast? Because these enzymes were not new, but mutant mutations in prior B-lactam genes.

Who would have predicted ten years ago that vancomycin, the last resort for therapy of multiply resistant Staphylococcus aureus and gram-positive nosocomial infections, would now be beset with an antibiotic resistance mechanism that comes in three forms, one of which is transferable?

Who would have predicted ten years ago, or even five years ago, that the new synthetic fluoroquinolone group of antibiotics, which were touted as the new "penicillins" and an answer to resistance, would be thwarted by resistance appearing in Pseudomonas, Enterobacteriaceae and Staphylococci. These drugs join the ranks of others with less than complete chance of treatment success. Resistant strains, despite localization of the determinant on the chromosome, have appeared worldwide.

What solutions have emerged in this disturbing scenario? Most notable was the creation of a Task Force study which evaluated "Antibiotic Use and Resistance Worldwide." Organized and supported by the Fogarty International Center of the U.S. National Institutes of Health, this three-year project, on which many APUA members worked, called information on six broad issues relating to the overall topic. A summary of this work was published in the May/June 1987 issue of Reviews of Infectious Diseases. To this day, the report is the best available summary of data on the status of antibiotic use and resistance throughout the world.

A long way to go

The see-saw game between bacteria and antibiotics continues, with the APUA. From a ten-year perspective, medicine has a new appreciation of the genetic fluidity of bacteria and how they can deal with antibiotic agents. From this perspective, besides the mutation of prior resistance genes there is, of course, the spread of bacterial resistance genes among species inhabiting different niches and among bacteria in which gene spread had never before been imagined. This perspective strengthens our resolve to learn to use these antibiotics more effectively and to deal directly with the problem of resistance.

What does APUA expect in the next ten years? It is not only about APUA increasing its membership, it is planning a Spanish version of the newsletter to meet the needs of the Southern American hemisphere. It is also hoped that the Alliance will progress to become a fully functioning data base providing a unique resource to the international scientific community.

APUA has come a long way in these ten years, supported entirely through its membership, who have collaborated in an international effort to deal with a critical public health problem. "There is still a long way to go," says the Alliance, "but the goals seem vital and achievable. It is through ongoing membership support that the organization will continue to educate its members and the world public and promote appropriate use of antibiotics everywhere. Tied in with this goal, and no less important, is to find the means to provide sufficient antibiotics to areas of the world where they are sorely needed but poorly available."

For further information about APUA work and membership write to: Alliance for the Prudent Use of Antibiotics, P.O. Box 1372, Boston MA 02117-1372, USA.
An Interview with Nigeria's Minister of Health

Minister of Health, Professor O. Ransome Kuti, on a recent visit to Geneva, spoke with EDM Editor, Ms Daphne Frelset, about Nigeria's strategy to rationalise drug supply and use.

EDM: What were the main areas of concern that led to the new drug legislation passed in December 1997?

RK: Firstly, under the new law any drug which is not on the essential drug list cannot be imported, manufactured, sold, exposed for sale, or distributed in Nigeria. Secondly, drugs have to be advertised and sold under generic names so that when the pharmacist labels the drugs the generic name must appear very boldly under the brand name; it should be at least three-quarters the size of the brand name. So that now if you come to Nigeria, and you see an advertisement for 'Paracetamol', for example, you see immediately underneath 'Paracetamol'. This also applies to television advertising. After the brand name is given it has to be followed by the words 'brand of' followed by the generic name. Another decree also made it a punishable offence to sell any drug which was found to be sub-standard or fake. We set up a task force, headed by an army officer, in all the Nigerian states, which went round checking market places and pharmacy shops to see that none of these counterfeit drugs were being sold.

EDM: How do you manage to check the quality of the drugs?

RK: One of our major deficiencies has been quality control. There is a newly appointed director of the Department of Food and Drug Administration and Control and the Federal Government has made US$ 2 million available to set up quality control facilities in various parts of the country. This should enable us to determine the quality of any drug within a very short time. We hope that this new investment will ensure that we establish an effective quality control service that can check the quality of any drug immediately that it is suspected.

EDM: So you will be checking both drugs coming into the country and those already on sale in the country in spot checks.

RK: Absolutely, and those manufactured in the country will also be checked.

EDM: I know that you gave a certain amount of time - I believe it was originally one year - for retailers to sell their existing stocks of drugs as a lead in to the full implementation of the legislation, and that this period was subsequently extended.

RK: That is so but the last August 1991 is now the deadline. After that date everyone must conform to the law.

EDM: In some other countries that have made radical changes in drug policy there has been considerable organised opposition, for example from industry and also from professional groups, to the new legislation. Did that happen in Nigeria?

RK: Doctors in Nigeria have not in any way opposed the essential drugs list. They are all now learning how to improve their prescribing habits. We are holding workshops on the rational use of drugs in our hospitals and doctors are now beginning to prescribe generically. As far as the doctors are concerned there is no problem.

The pharmacists are another matter. They mounted a spirited campaign of opposition. The first thing they said was that they were not concerned about the number of drugs in the country you are going to limit the ability of the doctors to prescribe. They said: "We are not complaining and they are the ones who prescribe, not you. Let the doctors complain first." So, they then said, "Why don't you use the list for the public sector and the private sector import any amount of drugs they like?" I said, "If you can demonstrate to me that the diseases affecting people in the private sector are different from those affecting the people in the public sector we shall adjust the list accordingly. Because, drugs are meant to treat diseases and if there is any difference in the incidence of disease between the private sector and the public sector, make a case and let the doctors present this case." Moreover, if any doctor finds that a drug needs to be imported for a particular case there is provision under the decree for a special permit to be requested. So we are not limiting the doctor in any way.

Any doctor who feels that the list is too restrictive should be prepared to propose amendments and to defend these in front of his peers. If the case is convincing they will support it. The essential drugs list is a health professionals' and not a vendors' list. The commercial pharmacists want to convince the public that the Government is trying to prevent them from getting the drugs that they need. I tell them that they are acting not as pharmacists but as drug sellers, which they don't like to hear. What we want is for them to practice the profession of pharmacy with its related professional ethics.

Then during my travels I am some-
industry, the pharmacists, the medical profession, lawyers, etc. were invited to participate in the development of the national drug policy. Other countries have adopted a somewhat different approach and legislation has been developed primarily within the government and with less participation from other interests because those countries felt that the pressure of different interests might weaken the eventual legislation. Then would you describe the Nigerian approach?

RK: It was the participatory approach. We invited all the various interests to a large workshop to develop the policy document. After initial discussions participants split into specific groups of professional expertise which formulated various policy components. In this way the document incorporated the ideas of the pharmacists, the doctors, representatives of the general public, etc.

EDM: Was it a harmonious meeting or were there some perceived conflicts of interest?

RK: I won't say there was much conflict. There were some disagreements about how to structure the new drug policy. In the past it used to be a free for all but now there is beginning to be some understanding that drugs should be available to everyone and that there must be some order in how they are prescribed, sold or used by the public. I think for that reason, by the time it came to writing the drug policy, the groups involved shared a common language.

EDM: We have found in the experience of the Action Programme, that the very process of developing a national drug policy in many cases has brought together professional groups who have had very little contact with each other before, and bringing those people together to interact and communicate is a strengthening process in itself.

RK: Exactly. I agree. And if you don't do that you are just asking for trouble in the future because they will denounce the policy. They will feel alienated from it and then in a way will not participate in the development of these policies and so we will have nothing to do with them. I think it is extremely important therefore to bring in as many people as possible and to convince them that you have a good case. This is the way to go.

EDM: Finally, how do you see the future development of Nigeria's pharmaceutical policy?

RK: I think we should proceed in an orderly manner. For example, we should first of all implement the Essential Drugs Decree. Then we need to implement and learn from the experience of our Essential Drugs Programme. We must begin to educate the public and get our doctors to adopt rational prescribing habits. Then the next step is to begin to manufacture our own drugs in support of our essential drugs policy. I think that is very important. And then we need to get the pharmaceutical industry to accept professional responsibilities so that they form the vehicle by which these drugs can reach the public and contribute to the solution and not the problem. I also believe that we must extend our system of quality control so that we can effectively monitor what is going on in the drug scene. These are the steps that I believe will enable us to reach our goal of ensuring the national availability and rational use of effective medicines.

EDM: Thank you. I am sure that our readers and many people throughout the world will follow pharmaceutical developments in Nigeria with great interest.

TREATMENT OF DISEASE

Diseases in Nigeria are treated by a variety of means. These include traditional medicine, Western medicine, and homeopathy. The traditional medicine is still widely used in rural areas, while Western medicine is more common in urban areas. Homeopathy is not widely used.

THE PRICE OF DRUGS

The price of drugs in Nigeria is determined by the drug manufacturers. The price of drugs is influenced by the cost of production, the demand for the drug, and the availability of the drug. The government of Nigeria has implemented a policy to control the price of drugs in order to make them affordable to all.

THE QUALITY OF DRUGS

The quality of drugs in Nigeria is determined by the drug manufacturers. The government of Nigeria has implemented a policy to control the quality of drugs in order to ensure that they are safe and effective.
Malawi: New drug legislation and National Drug Policy introduced

C.J. Forshev, P.J. Graaff, P.R. Khonje and P.S.P. Tembo

F or a considerable number of years, Malawi has been developing and implementing many of the key elements of a National Drug Policy. For example, a National Drug Committee was established in 1972 to advise the Ministry of Health on the selection of drugs for the public sector. One of its first duties was to devise a form of essential drug list which divided tablets, capsules and injectables for hospi-
tal use into vital and non-vital categories. This was several years before the World Health Organization developed its first model list of essential drugs in 1977. Malawi has also had a long-established tradition of using generics policy for the public sector in that generic names are used for procurement, prescribing and dispensing of drugs. For many years procurement has been achieved through national tenders and only one supplier is appointed for each drug class. This has been achieved through price negotiations and acceptable quality standards.

New legislation …

In 1985 it was decided that entirely new and comprehensive pharmaceutical legislation was necessary in order to put the National Drug Policy of 1972 on a legislative basis. The Pharmaceutical Act of 1985, which was partly modelled on the Pharmaceutical Act of the UK, introduced several innovative and progressive features.

Development of a national drug list and formulary …

In 1987 after a detailed review process and a great deal of preparatory work by the National Drug Committee, spanning several years, a fully comprehensive Malawi Standard Drug List was produced and widely distributed. This closely followed the World Health Organization's model list and covered all drugs and dose forms to be used in public sector health facilities. Items were listed by level of use according to the designations C (central hospitals), D (district hospitals) and H (health centres). This list contained some 260 items (including diagnostic agents and vaccines) in a total of 390 presentations.

In the same year, the revision of the draft of a formulary prepared in 1983 was completed by the National Drug Committee, and the first Malawi National Formulary was printed and distributed. This contained brief prescribing information on all D and H level drugs including indications, contraindications, doses, adverse effects and price codes given together with guidance on prescription writing, quantities to be prescribed, prevention of adverse drug reactions, and paediatric prescribing.

An essential drugs programme is launched …

In 1987 the Malawi Essential Drugs Programme (MEDP) was established as part of extensive World Bank support to the health sector. WHO was approached to draw up a plan of action and seek donor support for the new programme.

Initially priority was given to strengthening the drug logistics system through decentralization and rehabilitation of Central Medical Stores, improved transportation, and the building of district hospital pharmacies/drug stores. A preliminary draft of the Malawi Standard Treatment Guidelines and a revised edition of the National Formulary were also prepared.

As one of the requirements for World Bank funding of the MEDP, a comprehensive five-year National Pharmaceutical Plan 1990-95 was prepared by the Ministry of Health. This document detailed the current status, objectives, strategies, time-frame and budget for all areas of pharmaceutical activity and forms the basis for planning and implementation of pharmaceutical development over this period.

Promoting rational use …

With the improved functioning of the logistics system, focus on the MEDP then shifted to the promotion of rational drug use. The approaches include:

- improvement in diagnostic and prescribing procedures through implementation of an in-service training programme directed primarily at medical assistants and nurses at health centres and in hospital outpatients departments;
- improvement in drug management and dispensing skills through establishment of hospital drug management committees and in-service training of pharmacy assistants;
- an information, education and communication (IEC) campaign aimed at patients and the general public with the object of promoting rational use and storage of medicines and correct utilization of health services. This campaign will be long term and will make use of all available forms of mass media communication.

Further work was completed on basic reference and prescriber training materials with the publication of the Standard Treatment Guidelines in November 1990 and of the updated Standard Drugs List in May 1991. The National Formulary has been thoroughly revised and now includes useful information on all the items on the Standard Treatment Guidelines. A table on drug interactions has also been added. All these documents were prepared using desktop publishing facilities acquired under the MEDP. Because of this, future regular revisions will be greatly facilitated.

Written national drug policy …

Although commitment to an essential drug policy was implicit in the National Pharmaceutical Plan and the MEDP activities mentioned above, with the imminent implementation of the new Pharmacy, Medicine and Poisons Act, following gazetting of the Act in January 1991, the Ministry of Health considered that a written statement of national drug policy was now needed to provide a comprehensive and detailed framework for future pharmaceutical development, and to explicitly demonstrate the full commitment of the Government and the Ministry of Health in particular to the provision of effective pharmaceutical services through application of essential drugs concepts.

A draft was compiled by incorporating the relevant elements of the legislation into a structure based on several existing drug policy documents from other developing countries and on the WHO publication “Guidelines for Developing National Drug Policies”. A special meeting of the Pharmaceutical Services Committee, which is composed of senior government pharmacists and serves as a MOH advisory body, reviewed the working document. Although only minor changes were made, despite an intensive review, the participation of the members of such a committee is imperative in the creation of a strong body of professional support for active implementation of the policy.

National drug policy seminar …

The next step was to sensitize key decision makers from the public and private sectors to the implications of the new legislation, and to discuss the draft drug policy document in order to reach consensus prior to publication and dissemination. A three day National Drug Policy Semi-
The overall goal of the National Drug Policy is to:“to develop within the available resources, the potential that drugs have to control certain diseases and alleviate suffering.”

The two main objectives of the National Drug Policy are:

1. To ensure the ready and constant availability of high-quality, acceptably safe, and proven effective drugs at a price the individual and the community can afford.

2. To rationalize the use of these essential drugs through the provision of improved drug utilization information, training of health professionals, and education of the public in the appropriate drug use and storage, with the aim of rationalizing drug supply management, prescribing, dispensing, and improving patient compliance.

Policy areas covered in the National Drug Policy include: public administration, drug selection, financial resources, drug procurement, local drug manufacture, drug distribution, drug storage, inventory control, quality assurance, drug legislation, rational drug use (including training, drug information, prescribing, dispensing, patient compliance and self-medication), and disposal of waste materials. Drug advertising and promotion, research and development: monitoring and evaluation, intersectoral cooperation and technical cooperation with other countries and international agencies.

An introduction summarises existing problems with regard to drug supply and use, including funding shortages, drug supply management, storage and distribution deficiencies, irrational drug use by health professionals, patients and the general public, acute shortages of trained health personnel of all categories, deficiencies in record-keeping, and shortage of drug information materials, and mentions steps taken so far by the MOH to rectify this situation. Important features of the policy include:

- For public and private sectors, the procurement of drugs, including donations, will be limited to items registered for use in Malawi and also registered for use and currently marketed in their country of origin. Certain drugs for treatment of specified tropical diseases may be exempted from the latter requirement. Donated drugs must have at least 18 months shelf life remaining and be labelled in English.

- Local private sector suppliers will be required and foreign suppliers requested to label their product packages with the generic name prominently displayed adjacent to and at least one third the size of any brand name.

- Drug procurement for the public sector is by generic name only according to the Malawi Standard Drug List.

- The national pharmaceutical industry, both public and private, will be provided by means of various incentives with the overall goal of increasing self-sufficiency in the production and packaging of essential drugs and reducing the dependence on foreign supplies.

- While local industry will continue to receive preferential treatment in procurement, the government will also ensure that their participation in the development of an identified range of bulk essential drugs by requiring that a particular proportion of their annual output be devoted to the production of those items, as well as by their compliance with the requirements of Good Manufacturing Practice (GMP). Contract failures to comply with the latter will result in the loss of the manufacturer’s licence.

- In the area of rational use the policy details measures and activities concerning training, drug information, prescribing, dispensing, patient compliance and self-medication, and expects disposal of waste materials. Hospital drug management committees (HDMCs) are also to be set up in all hospitals and will include the senior clinicians, senior nurses, senior accountant, and senior pharmacist, or in their absence and depending on the nature of the hospital, their nominated representatives or equivalents. The HDMCs will have a wide range of duties concerning the availability and rational use of drugs in their institutions and in the peripheral units they oversee. Summary guidelines for the functioning of these committees have already been issued by the pharmacological services section of the MOH and their activities will be closely monitored and regularly evaluated.

- Drug advertising and promotional activities must be in line with rational drug policy objectives and will be carefully controlled. Ethical criteria will be established and published and the drug inspectors will monitor such activities to ensure compliance with the criteria. Public advertising will be restricted to the over-the-counter (OTC) medicines, and promotion of POM and P items will be limited to professional health journals. All advertising and promotional material will be vetted by the Board which must grant approval prior to use of the material. Whenever a brand name of a product is used in any form of promotional or advertising material (including broadcast material), the generic name of the drug must be given due prominence.

- The range of activities of the national pharmaceutical services administration will be extended to include provision of Drug Information Services, Adverse Drug Reaction Monitoring and a Poison Information Service.
Major Features of the Malawi Pharmacy, Medicine and Poisons Act

Pharmacy, Medicine and Poisons Board
Establishment of a Pharmacy, Medicine and Poisons Board, with the following members: the Chief of Health Services and the Chief Pharmacist (both ex-officio members), 3 pharmacists (representing the public and private sectors), one medical practitioner, one veterinary surgeon, and one nutritionist. The main functions of the Board are to act as the sole registering authority for medicinal products and all persons registered under the Act, to exercise discipline and control of all registered pharmacy personnel, to accredit and provide the standards of pharmacy training activities, and to advise the Minister on any matters falling under the Act.

Registration
Introduction of medicinal product registration for each new form of each drug circulating in the country, including dosage forms. It was noted that as of January 1st 1993, only registered products will be allowed on the market. Criteria including safety, efficacy, quality, cost, and therapeutic need, will be taken into consideration. The Board will not register on the market.空白

Pharmacy personal Registration of pharmaceutical personnel will be extended to include pharmacy technicians and pharmacy assistants as well as pharmacists.

Categorization of drugs
Scheduling of medicinal products into groups for the purpose of control of sale and supply. These will be: Prescription-only (POM), Pharmacy-only (Py), General sale list (GSL), Controlled drugs (CD). The Board will also compile restricted lists of medicinal products which may be prescribed by paramedical personnel such as medical assistants, clinical officers, midwives and nurses.

Promotion
Regulation of pharmaceutical sales promotion and advertising and of the activities of drug company representatives.

Labelling
Provision of labelling requirements applying to the sale, supply and dispensing of medicinal products.

Cosmetics
Control of cosmetics importation, especially where products are potentially harmful.

Penalties
Establishment of stiff penalties for contravention of any parts of the Act.

New outpatient pharmacy at Machinga District Hospital, Malawi.

This and at least one third the size of the trade name (the original proposal was for the names to be of equal size). Advertising hoardings, billboards and similar types of advertising will be included in this requirement and where trade names are used in broadcast advertising (radio, TV) the generic name of the active ingredient(s) should be given with a description in the body of the advertisement. It was noted that problems may arise with these requirements in respect of combination products. The Board will consider these and come up with suitable recommendations.

Generic prescribing
In order to encourage this, it was agreed that the MOH would issue suitable official abbreviations for certain drugs with long names, such as penicillin, cotrimoxazole, chloroquine.

Product substitution in dispensing
It was agreed that pharmacists could substitute an equivalent generic or other brand name product for a prescribed brand name product which was not available in circumstances where the prescriber could not be readily contacted, but that the prescriber should be notified of this as soon as possible. With illiterate or uneducated patients in particular, confusion and doubt may result if they are told that they are receiving a “different” medicine from the one prescribed. Therefore it will be left to the pharmacist to use professional discretion in deciding whether to also inform patients of such a substitution.

Disposal of waste products
It was decided to add a new section to the policy which would cover the correct and safe disposal of pharmaceutical, surgical and medical waste, including expired or unused drugs, used containers, used needles and syringes, etc.

Training needs
It was agreed that training was a vital part of efforts to improve drug handling in general and that training programmes should consider needs in the private as well as public sector. The need for updated diagnostic training for prescribers was emphasised as well as health unit management training, including stockkeeping and management of drug supplies, the latter also for pharmacy assistants and stores managers.

A significant impact...

With the publication of the National Drug Policy, all the required main components of an essential drugs programme for Malawi are now in place. It is hoped that once the acute pharmaceutical human resources shortage is overcome through an extensive programme of training of pharmacy graduates, pharmacy assistants and technicians, and provided sufficient funds can be secured for the required essential drugs, the result will be a greatly improved provision of pharmaceutical services with a significant impact on the health of the population.

Diabetes with the text of the Malawi Standard Drug List, the Malawi Standard Treatment Guidelines, the Malawi National Formulary and the Malawi National Drug Policy can be made available in Malawi.

*Professor Roma Khandje is Controller of Health Technical Support Services, Mr. Patrick Tembo is Chief Pharmacist and Mr. Chris Furse is Principal Pharmacist with the Ministry of Health, Lilongwe, Malawi. Mr. Peter Gruff is the WHO Project Adviser for the Malawi Essential Drugs Programme.

Plenary session at Malawi’s National Drug Policy meeting.
Recent Research

Drug information for patients in the community

D. Chuvunduka, M. Dzimwasha, F. Madondo, E. Mafana, A. Mbewe, & N. Z. Nyazema

The failure of patients to follow drug regimens may be due to lack of information or the negative attitudes of patients and health care providers. We have found that most patients in rural areas did not ask for information about their treatment because they felt their health care workers had little time for such matters. These problems will persist unless practitioners at all levels make better efforts to understand their patients’ perceptions of illness and treatment, and especially whether compliance with drug treatment is feasible.

The failure of patients to keep to a well-founded drug regimen is one reason for unsuccessful treatment. In the developed world up to half of all patients do not take drugs as prescribed and may stop treatment prematurely when they feel better. This may be a deliberate act by the patient; or it may occur through misinterpretation or inadequate information. Compliance is known to be higher when patients have some understanding of their condition and treatment: verbal instructions which reinforce any written information may increase knowledge and improve compliance. In one study carried out in the Orange Free State (South Africa), 83.6% of the patients interviewed felt that more involvement on their part would lead to greater trust in their health care provider and more confidence in the treatment. To eliminate low compliance, the health care provider must first determine what the patient is willing to accept the treatment and then decide what kind of information he or she needs on the drugs given. In general, health care workers tend to respond only to specific questions the patients may ask. In a baseline study we found that only 20% of patients received some kind of drug information from their community health team.

Household survey...

We therefore decided to investigate the extent to which patients were given detailed information about their treatment, the primary source of this information, and the type of information which they sought out on their own initiative.

Using systematic cluster sampling, we studied 910 households in urban (300), rural (300), and commercial farming (310) areas in the Mashonaland West Province of Zimbabwe. Whenever possible, heads of households were interviewed with a standardized questionnaire concerning the following:

- knowledge about common diseases in the community, e.g., etiology;
- health-seeking behaviour;
- medication taken;
- type and source of medication;
- type of information given by health worker.

The interviews covered all relevant drugs and remedies; with each drug mentioned, we recorded whether it was available over-the-counter or on prescription only. Details of traditional remedies were also noted to see how these were perceived by the respondents as compared to those of proprietary medicines.

The questionnaire interviews were followed a few weeks later by group interviews on the same topics. This allowed us to verify and supplement the data obtained earlier. As far as possible, members of all the groups sampled were representative for age, sex, education levels, religion and socioeconomic status.

Medication knowledge...

The diseases or symptoms most commonly recognised in both rural and commercial farming communities were diarrhoea, influenza, coughs, hypotension, and malaria. The respondents were also aware of chronic conditions such as epilepsy, asthma, and diabetes. In general, the illnesses were ascribed to natural or supernatural causes. These views on etiology determined the health-seeking behaviour in both rural and urban populations who, on the basis of previous experience, tended to choose a form of therapy which they believed would help a particular disorder.

The desired information concerning their health problems was related to the respondents’ personal history. Some 80% of the rural people claimed not to trust their health provider and did not ask questions about the medication or therapy.

Most of those interviewed in rural districts and commercial farms were semi-literate. In contrast, 60% in the urban area had some general knowledge about the action of various medicines and were aware of their high cost when private practitioners or pharmacists issued the prescription. There were no private pharmacies in the rural areas, and drugs were either bought from a general store or obtained from the rural health centre. As to why a majority of the rural sample felt there was no need to have further information on medications apart from details about dosages, the reasons given included:

- health carers were too busy to explain;
- the information was too difficult to understand;
- the patient was too ill to discuss anything at the clinic or hospital.

When questioned about the kind of general information they would like to have about medication, the respondents suggested the following:

- Cause of the disease.
- Treatment schedule and duration.
- Names of prescribed drugs and the best way to take them.
- Action to take when there are side-effects.
- Proper way to store the medicines.

The specific types of drugs requiring more detail were:

- anti-infective agents, e.g., penicillins, chloroquine;
- non-steroid anti-inflammatory drugs, e.g., acetylsalicylic acid.
- vitamins;
- cough mixtures (expectorants and antitussives).

How, why and what?...

A number of studies in different social settings have addressed the issues of how much patients should be told about the drugs they take; whether there should be written material about medication; how much the information best be given, and who should give it. Two different conclusions have been drawn from the results of these earlier studies: the first argues that giving information to an illiterate person is pointless, since the patient is unlikely to understand or be interested in details. This view is supported in part by the results of our group interviews from our study. In contrast, the other holds that patients are unable to make appropriate decisions and are less likely to comply with treatment regimens unless they are fully informed about their condition and its treatment.

However, perhaps the choice is neither to resign in the face of illiteracy nor to give out routine and standardized information to every patient with a given condition. In the same way that drug dosages are individualized, details and information about medication should be tailored to match the needs of each individual patient.

Not only is it important to determine whether patients understand the nature of their health problem before details of medication are given, the health care workers should also be aware of their patients’ beliefs about illness causation. A large body of empirical literature suggests that attitudes and beliefs contribute substantially to a patient’s decision whether to cooperate with treatment plans. It has been claimed that these beliefs can be readily assessed and often altered. However, our results suggest that this process may be difficult especially with semi-literate people who still hold strongly to traditional attitudes concerning health and illness. Many people still believe that diseases can be of supernatul origin. This has obvious implications for modern pharmacotherapy in particular and for health-seeking behaviour in general.

It is noteworthy that a majority of the rural population (71%) did not request any information about their medication because they felt that the health care worker had no time for discussion. More seriously, other care providers were thought to be extremely ill-mannered and the patient decided not to ask for more information in order to avoid unnecessary conflict.

In developing countries like Zimbabwe, there are few pharmacists who can support a patient’s ability to recall oral information.

Continued on Page 16
Uruguay: First AIS Training Course

Since 1987, the Latin American and Caribbean Network on Health Action International – Acción Internacional Para la Salud (AIS) – has been working for the rational use of drugs and the implementation of essential drugs policies in Latin America and the Caribbean. AIS, which is supported by the International Organization of Consumers, now includes 14 countries of the region, 13 of which were represented at a first AIS training course held in Montevideo, April 1991.

Regional participants were joined by representatives of WHO’s Action Programme on Essential Drugs, the Pan American Health Organization and HAI-Europe, in an intensive week of practical workshops and discussions.

Workshop topics covered network organization, project writing, pharmacoepidemiology and pharmacotherapy education, the compilation of a regional essential drugs list, consumer education, essential drugs policies, influencing authorities, drug campaigns and use of the media.

A set of WHO reference and information materials was provided by the Action Programme for each participant.

Regional advances: a five year review

Argentina:
Representatives reported major progress: essential drugs lists had been compiled and applied for different levels of health care, and curriculum changes had strengthened the teaching of pharmacoology at the university level. In 1988 the first national seminar on essential drugs was held in Cordoba, organized by the “Movement for a Global Health System” (MOSIS). This was followed by a second seminar in 1990. Among other activities, the Argentinean AIS networks are supporting a study on the use, consumption and cost of antibiotics in hospitals.

Ecuador:
AIS-Ecuador successfully campaigned for a revision of the clinical pharmacology syllabus at university level, to include the rational use of drugs and permit students to make practical application of their knowledge.

The network was also consulted by the Government during its recent review of pharmaceutical legislation.

Bolivia:
All the activities are now so widespread that the network has become a reference for many health professionals.

Peru:
Network activities have also had an impact at the university level in Peru, an influence which has been reflected in the increasing frequency of students choosing to research the irrational use of drugs as their thesis topic.

Brazil:
The “Group for the Prevention of Irresponsible Use of Drugs” in Fortaleza has been working on the provision of drug information for the general public. The group has also been investigating and publicising the dangers of the current widespread use of misoprostol (an antifunerecic) as an abortifacient. The results of the investigations were widely publicised, nationally and internationally, through published material and seminars with health professionals.

The network has been working closely with the media through the “Drug Group”, collaboration which led to substantial television coverage of issues related to the drug use and misuse.

The publication of “Searching for a Remedy”, a comprehensive 400 page therapeutic manual for health care workers, has provided a significant training resource for health staff working in isolated areas who lack specialised training. 6000 copies will be distributed and used in training courses. Plans are now underway to use it as a model for the development of training material in other countries of the region.

Looking to the future

New working groups:
Future activities include the formation of working groups on:

- women’s health care
- education of health workers
- the compilation of a unified drug list for Argentina, Brazil, Paraguay and Uruguay, members of the regional Common Market which will start operating in 1994;

The treatment of patients in societies with strongly held indigenous beliefs systems might require either appeals to their family responsibility or the provision of information from more credible sources: for example, testimonials from patients where the same treatment had proved successful. We found this to be the case with men who had contacted sexually transmitted diseases and where details of treatment had been relayed from one man to another.

It is not surprising that some literate people, particularly those from the urban area, did not place a high value on oral information, claiming that it was too easily forgotten. However, other studies have shown that well-structured counselling can improve the ability to recall information.

A complex process...

Decisions about treatment are often more complex than is commonly supposed, both by the health worker and the patient. This approach to the situation with degrees of uncertainty, practitioners are likely to have information which may be valid at the time but which can become outdated as medical knowledge improves. Equally, when a patient takes a drug he or she is taking part in an experiment where the outcome might not be fully understood. Furthermore, the patient may be uncertain about the implications of the diagnosis and its suggested treatment.

Therefore, a constructive dialogue between the health care provider and the patient is required irrespective of whether the patient is illiterate or not. We consider that the reluctance of many illiterate women to learn more about oral contraception represents such a challenge to health workers.

Details about medication for patients in a given community must be structured to take heed of local conditions. It is important to recognise that a wide gap can exist between the objective knowledge of health care providers and the more subjective experience of their patients. Practitioners who fail to make use of the patient’s fund of experience and expertise will do so to their own and their client’s disadvantage.

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References
APHA initiative to support WHO Action Programme

At its 118th annual meeting in New York, 30 September-4 October 1991, the Governing Council of the American Public Health Association (APHA) adopted a position paper entitled "Medicines in Developing Countries: A Global Health Concern" as official policy of the Association. APHA represents a combined national and affiliate membership of 55,000 public health professionals and community health leaders in the United States.

The goal of the initiative is to increase support for the promotion of rational drug use as an essential component of primary health care in developing countries, and to increase recognition of the central role of the WHO Action Programme on Essential Drugs and Vaccines. The Association recognizes that WHO has included among its goals the availability at the primary health care level of the most needed essential drugs and vaccines and improved rationality in their use. It emphasizes that global cooperation is required to solve the problems revealed by a 1988 WHO analysis indicating that between 1.3 and 2.5 billion people have no regular access to essential drugs, and that there is excessive misuse of available medicines.

Policy objectives...

The new policy has three specific objectives:

1) relative to the pharmaceutical industry:
   □ to ensure that the ethics code of the International Federation of Pharmaceutical Manufacturers’ Association (IFPMA) is applied to exported drugs and that all possible pressures are brought to bear upon violators by both the IFPMA and the national authorities of all countries;
   □ to support theraham of codes of ethics and drug regulations for locally manufactured drugs;

2) relative to the WHO Action Programme on Essential Drugs and Vaccines:
   □ to institutionalize financial support so that the Programme has a more stable financial base;

3) relative to Member States of the WHO:
   □ to ensure that exported drugs meet accepted standards of safety, efficacy, and labelling;
   □ to support WHO’s guidelines on ethical criteria in drug promotion;
   □ to provide technical and financial support for the routine collection of epidemiological data needed to estimate drug requirements and for systems of drug use review in developing countries;
   □ to provide technical assistance for evaluation of drug cost recovery schemes;
   □ to provide technical assistance for the development of local and regional drug production capabilities;
   □ to assist the development and dissemination of drug education materials for health professionals and for the general public.

WHO’s World Drug Situation reports that between 1.3 and 2.5 billion people have no access to a regular supply of essential drugs.

Working nationally and globally

Under the new policy, the APHA is planning a range of activities with national and international implications which will:

- promote the policy goals through its formal association with the World Federation of Public Health Associations (WFPHA) and collaboration with WHO;
- establish an advisory group to promote the desired actions through the WFPHA, the WHO, other organizations, and the United States Congress;
- develop and communicate the APHA policy to international, national, and local audiences;
- develop strategies to encourage all transnational drug companies, especially those based in the United States, to cooperate with the WHO to achieve its goals relative to essential drugs programmes in developing countries;
- educate the US Congress about APHA’s position, encouraging legislation that would support the desired actions, especially relative to export controls, technical support, payment of the United States contribution to the WHO in full and on time, and the extrabudgetary needs of the WHO Action Programme on Essential Drugs and Vaccines; and establish a mechanism to monitor the global drug situation and health impact relative to drug access and rational use.

The policy and related activities were presented by Dr Patricia J. Bush of Georgetown University School of Medicine at the Pharmacy World Congress in Washington, D.C., September 1991.

APHA is working closely with the World Federation to build consensus on the need to provide strong support to the WHO Action Programme on Essential Drugs. The World Federation discussed the issue at its annual meeting and distributed the position paper to public health organizations in 48 countries with an explanatory letter requesting comments. In addition, more than one hundred international and national pharmaceutical associations worldwide have been contacted, together with a large number of individuals known to be interested in the issues concerned.

The Office of Technological Assessment of the United States Congress will also be requested to monitor the global drug situation and its impact on health.

A new APHA advisory group

An Advisory Group on Medicines in Developing Countries has been formed by the Association under the aegis of the Drug Policy and Pharmacy Services Committee, Medical Care Section. The new group will hold its first meeting in Atlanta, Georgia, 10-14 November 1991, chaired by Dr Albert Wertheimer, Dean of the Philadelphia College of Pharmacy and Science, and will work with APHA to implement the actions called for in the policy paper.

The full text of the APHA policy paper is published in the American Journal of Public Health, 81(2):256-260, 1991, or individual copies may be obtained by writing to Mr. Jeff Jacobs, Governmental Affairs, APHA, 1105 15th St, NW, Washington, D.C. 20005, USA. For further information on the work of the Advisory Group contact Dr Albert L. Wertheimer, Philadelphia College of Pharmacy and Science, Woodland Ave at 43rd St., Philadelphia, PA 19104-4495, USA.

GHANA:
Subregional drug quality control laboratory opens

Following support from WHO’s Regional Office for Africa, Ghana has just announced the opening of its sub-regional drug quality control laboratory at the Ghana Standards Board, Accra. Ghana now joins Niger, Cameroon and Zimbabwe all of which are now able to provide quality control facilities for neighbouring countries. The project, started by WHO in 1985, is aimed at improving quality assurance in the African Region through the upgrading of national laboratories to international standards.

Ghana’s new sub-regional laboratory is equipped to deal with most drug quality tests, especially those which cannot be handled locally in some neighbouring countries. In the future the laboratory will also be used for in-service training or refresher courses for drug quality control personnel.

For further information contact: The Director, Ghana Standards Board, PO Box M-245, Accra, Ghana.
**NEWSDESK**

**Generic use increasing in Indonesia**

The use of government-approved generics, officially recognised by a specific logo on their packs, is increasing in Indonesia, according to Health Minister Dr Adhyatma. The generics are produced by the three state-owned companies, Pphap, Kimia Farma, and Indo Farma.

The Government is attempting to encourage the use of generics to contain healthcare costs, having implemented legislation on their use in 1989. Dr Adhyatma has suggested that the increasing demand will be met by involving those private-sector companies (currently four) which have obtained a GMP certificate.

Production in Indonesia in the first half of 1990 rose by 35.9% on the corresponding 1989 period to Rp16,257 million (58.6 million). Production in 1989 was Rp11,981 million, and that in 1990 is expected to reach Rp38,200 million. Generics cost 30-40% less than branded products (after allowing for promotion costs, overheads etc.), but make only a 5% profit, Scrip's correspondent reports.

**Source**: SCRIP, Jan. 18, 1991

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**Norway lists generic preferences**

Since the beginning of April Norwegian doctors have been obliged to prescribe the “cheapest” of multi-source products. “Cheapest” is defined as any product which is not more than 10% more expensive than the very cheapest.

As an aid to selection the regulatory agency has published a list of multi-source products in the latest issue of Nyt fra SLK. In this list the “cheapest” products have their names printed in bold capitals.

The list covers the “economically most significant” compounds, says the SLK information: diliazem, methylidopa, nifedipine, prazosin, verapamil, fosamprenavir, ibuprofen, atorvastatin, amiodarone, ondansetron, nitazoxanide, plicamycin, cefotaxim, tetracaine, ketorolac, ciprofloxacin, ranitidine, propranolol.

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**Source**: SCRIP, May 22nd, 1991

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**Aberdeen: drug management courses for 1992**

Two courses in effective drug management and national drug use will be held at the Robert Gordon Institute of Technology from 20 January to 10 April, and from 7 September to 27 November 1992, in collaboration with WHO’s Action Programme on Essential Drugs.

These courses are oriented to meet the needs of pharmacists from developing countries and cover such areas as national drug policy, drug selection and procurement, stock and financial management, and standard treatment schedules.

See EDM-11 for further details or write to: School of Pharmacy, Robert Gordon Institute of Technology, Schoolhill, Aberdeen, Scotland, AB2 1FR, UK. Telephone: 0224 535341. Fax: 0224 635559.

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**Drugs storage is often far from optimal as this scene from a subsidiary health centre in Madhya Pradesh, India shows.**

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**Essential drugs in South-East Asia: past, present, future**

Senior government officials from ten countries of the region, together with WHO staff from the Regional Office and Heads of mission, met in New Delhi from 4-8 March in a first ever regional essential drugs meeting to review progress in their countries’ essential drugs programmes, identify future needs and outline long-term plans for national and regional collaboration with WHO.

A focus on the rational use of drugs, to include curriculum development for health professionals and the provision of drug information for prescribers, pharmacists and the general public, were highlighted as priority needs. Participants also called for use of the revised WHO Certification Scheme, training in estimating drug needs, a regional meeting of drug regulatory authorities, and the development of indicators to measure progress in the various components of an essential drugs programme.

**Review of the eighties**

After a global and regional overview of socioeconomic aspects of essential drugs programmes case studies were presented on:

- action programmes on essential drugs in Bhutan and Myanmar;
- trends in the development of pharmaceuticals in the next decade in India, Indonesia and Thailand;
- quality assurance in Mongolia, Nepal and Sri Lanka;
- availability of essential drugs in primary care: problems and constraints in DPR Korea, Indonesia, Myanmar and Maldives.

Participants then split into groups to discuss the drug situation in each country, examining problems and constraints, and the national and international inputs required for such essential drug programme components as: national drug policy; legislation; national essential drug list: procurement, storage and distribution; quality assurance; information systems; human resource development: monitoring mechanisms, and production. The need for training and human resource development in all components was emphasised throughout the meeting.

Eight of the ten participating countries, it was found, had a defined national drug policy, with only two requiring WHO collaboration to develop their policies. Although a drug act existed in all the countries human resource training and support was needed by most for development of the regulatory control system. All countries had adopted, and six countries fully implemented, national essential drug lists for each level of health care, but research was needed on the use of the lists.

**Planning for the nineties**

Major overall recommendations from the meeting were:

- that all countries should strive to attain 100% coverage with essential drugs at primary health care level, strengthen their quality assurance system, and increase budget allocations for national drug programmes based on needs;
- that each country should develop an independent unit within the health directorate to monitor and evaluate its essential drugs programme in terms of coverage, quality assurance and rational use of drugs;
- that WHO should promote technical cooperation between countries in human resource development, quality assurance, pharmaceutical technology and herbal medicines;
- that WHO should continue to provide technical support and mobilize funds for development and strengthening of action programmes on essential drugs, particularly in the least developed countries in the Region.

The meeting provided an excellent forum for a frank exchange of experience and to examine problems and solutions within both a national and a broader regional context. It also helped WHO to plan specific future country support and regional activities. Similar meetings are planned in the other WHO regions.

A full report is available from: WHO Regional Office for South-East Asia, New Delhi, or the Action Programme on Essential Drugs, WHO, Geneva. A separate report with edited versions of the country case studies is under preparation.

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**NEWSDESK**

**EASTERN MEDITERRANEAN:** Regulators discuss their role in national drug policy

Representatives of drug regulatory authorities from countries throughout the Eastern Mediterranean gathered in Nicosia from 10-13 June 1991 to discuss common problems, learn of new initiatives, and identify means by which they can assist in the development and implementation of a national drug policy. The meeting was organized by the WHO Regional Office for the Eastern Mediterranean with technical and financial assistance from the Action Programme on Essential Drugs, a regional forum whose report would be presented at the International Conference of Drug Regulatory Authorities the following October.

Cyprus Minister of Health, Dr Panikos Papageorgiou, opening the meeting, spoke of his concern about the increasing price of newly developed drugs, overprescribing by doctors, dispensing of drugs without prescription by pharmacists, and the misuse of antibiotics and psychotropic drugs. The approach of the Pharmaceutical Department in Cyprus to improve this situation is a mixture of strict control, persuasion and information. National drug policy in Cyprus is part of the national health policy, he told participants.

Over four days of intensive discussions participants spelled out the role and responsibilities of drug regulatory authorities with respect to national drug policy. Specifically, the development of a national drug policy should start with the formulation of its objectives. These would usually be to ensure the availability of essential drugs of good quality and affordable cost to all people, and to promote the rational use of drugs. At the same time, other objectives may be formulated, such as the promotion of a national industry, the reduction of the number of drugs in the market, or the use of generic names.

The adoption of these objectives will usually imply that political choices have to be made and priorities set. The drug regulatory authority, or the department of pharmacy in the ministry of health, is the logical body to start the discussion on the national drug policy, to involve all parties concerned, to present the various policy alternatives, and to seek an agreement and the political will.

After the policy has been formulated it should be supported by adequate legislation, for example, in the field of quality assurance, registration and inspection. Such legislation, which will provide the legal framework, should then be translated into and supported by regulations, which are more detailed and flexible. The DRA should prepare such legislation, and especially, issue practical and enforceable regulations.

In the field of drug supply, drug regulatory agencies (DRAs) can be instrumental in two areas: selection and national production. In the area of drug selection for the public sector, the DRA can assist in the development of supply lists, indicating the range of drugs that should be available for each level of health care. In the private sector, the DRA should issue guidelines and criteria for the registration of drugs, which, for example, could express a policy to discourage the use of combination drugs, promote generic products, limit the number of drugs on the market, etc. The DRA is, of course, the main body for the evaluation and registration of drugs, and the inspection of the supply chain. With regard to local production, the DRA can support the national drug policy by means of a pricing policy, regulation, licensing of premises and good manufacturing practices (GMP) inspection.

Quality assurance forms another major focus of DRA responsibility which will include the evaluation and registration of drugs, inspection and quality control.

Finally, discussions highlighted many ways in which drug regulatory authorities could support and implement national drug policy in the area of rational use. The rational selection of essential drugs, both for the public and the private sector, would reduce the number of irrational therapeutic alternatives available to prescribers.

The supply of drug information in the form of a national formulary and a drug bulletin or therapeutic newsletter is another important DRA responsibility. The DRA should also develop regulations for advertising and promotional activities. And it should promote the involvement of all parties in the NOP and the dissemination of relevant drug information through national seminars.

Drug regulatory authorities should take on the responsibility to initiate the development of a national drug policy, concluded the meeting. They should prepare the necessary legislation and regulations, and also coordinate the implementation of all components of the policy. All concerned parties should be involved in this process.

WHO is very well equipped and ready to support governments in this important task, the meeting was informed.

**PAKISTAN:**

Misure of drugs for childhood illnesses

Concern about the misuse of drugs in paediatrics practice was expressed at the annual meeting in June of Pakistani practitioners from all over Pakistan, reports Dr Alm Photograph by Saeed Saifuddin.

A survey from Peshawar found that 90% of general practitioners were using antibiotics and antidiarrheals to treat acute diarrhea, while oral rehydration therapy was underused. Another study of drug use in acute respiratory infections revealed indiscriminate prescribing of antibiotics and cough syrups by almost all practitioners. The most important factors contributing to the widespread misuse of drugs in the country were low availability of prescription medicines over the counter, heavy marketing of drugs by pharmaceutical companies, and drug sales by general practitioners to their patients. Traditionally, there is no charge for the consultation itself.

In a strongly worded resolution addressed to the Government, the general assembly of the association made recommendations to rationalise the use of drugs in the country, emphasising the need for special care in prescribing for children. The resolution deplored the unnecessary health risks and the unacceptable waste of scarce resources represented by the large numbers of harmful and ineffective drugs available in Pakistan and called for an end to sales of such products. Antidiarrheals, antipyretics, stimulants, brain stimulants and liver "tonics" were specifically named, as were imported drugs not allowed in the country of origin and those having very limited indications. The barriers of commercially available herbal drugs were also noted, and the resolution called for them to be regulated within the drugs act.

The association also requested the Government to draw up and adopt a list of essential drugs and vaccines and to engage the cooperation of the pharmaceutical industry in producing urgently needed drugs for all Pakistan's people. Finally, the paediatricians recommended that clinical pharmacology be taught at undergraduate and postgraduate levels. At present it is not.

The call to the Government for effective measures to control medicines and to ensure their rational use, says The Lancet, followed a disturbing report in which a paediatrician attributed the deaths of six babies to misuse of loriodam in its paediatric formulation (Lancet 1990; ii: 363, and 1990; ii:314).

The Ministry of Health subsequently deregistered all drop and syrup formulations of loperamide as well as several other antidiarrheal drugs. Paediatricians were the group that played the leading part in the pressure for this change, says Philippus Saunners.

*A* [fact, Pakistan did draw up an essential drugs list in 1989 with WHO technical support, but this was not implemented. Ed.]

**Street theatre in Germany**

BUKO Pharma-Kampagne's street theatre group toured throughout this summer. Drama included a German tourist who dies after taking deiprose: a play based on a popular TV quiz show, asking questions about the proportion of irrational and dangerous drugs exported by German companies; and an opera on injectable contraceptives called the "Zaubererspritzte" or The Magic Shot based on Mozart's opera The Magic Flute.
Essential Drugs Monitor

NEWSDESK

New Journals

Drugs Today

This bi-annual update on rational drug use, whose first issue appeared in June 1991, is published by the Christian Medical Association of India. Its goal is to sensitize professional groups, the government and consumers to the many topical issues related to drug supply and use.

Dr. Molly Thomas, editor of Drugs Today, and Professor of Clinical Pharmacology at the Christian Medical College and Hospital, Vellore, says that the newsletter aims to:

- Educate and build awareness among professionals and non-professionals on drug use in the community;
- Develop methods of better pharmacy management and a simple hospital formulary;
- Provide guidance on the acquisition of low cost drugs of good quality and rational prescribing and dispensing;
- Encourage the use of generic names at all stages of packaging, prescribing and dispensing drugs;
- Collect and publish data on adverse drug reactions.

The newsletter will network with other agencies to motivate wide community involvement in all these issues.

For further information contact: The Publications Desk, Christian Medical Association of India, Plot No 2-A, 3-Local, Shipping Centre, Janapuri, New Delhi, 110058, India.

Rational Drug Bulletin

This bulletin, which appears quarterly, is produced by West Bengal’s Community Development Medical Unit (CDMU), a non-profit organization providing low cost essential drugs to member organizations working in the voluntary health sector. CDMU has been working towards rationalizing drug use for some time through seminars, workshops and printed materials. It now hopes to reach out to the public to increase awareness in a much wider way through the new bulletin.

Rational Drug Bulletin will have regular articles on essential drugs, irrational drugs, abuse or misuse of drugs, and recent advances in the field of health and medicine. Doctors will be urged to prescribe drugs by generic name, and to avoid branded and high priced drugs.

Each issue will highlight one problem drug, with appetite stimulants chosen as the subject of the first in the series. Issue No. 1 also covers the use of benzodiazepines for anxiety, the choice of antimicrobials, and a very useful table indicating first choice antimicrobial drugs and alternatives for infections, listed according to pathogenic organisms.

If you would like to subscribe to Rational Drug Bulletin contact: Community Development Medical Unit, 80-c, Dr Sushil Sarker Road, Enclave, Calcutta-700014, West Bengal, India.

Health Action

AHRTAG newsletters - Dialogue on diarrhoea, AIDS Action, CBI News, CBR News - have so far focused on specific areas of primary health care. Health Action, AHRTAG’s latest publication, whose first issue appeared in June 1991, will take a broader perspective on how PHC fits into health care systems, and how health is linked to other aspects of development, providing an international forum for the exchange of ideas.

Editors Suzanne Fastukain and John Macdonald, introducing the first issue, write of the economic pressures which in the 1980s have made many communities throughout the world increasingly vulnerable to ill health and disease. For the poorest, living standards have worsened as real incomes have fallen. International debt and the restructuring of national economies have also led to widespread cuts in public services including health care. In this difficult global environment, how can the goals of PHC and Health For All in the 21st Century be realized in Africa, Asia and Latin America? How can PHC be raised to remind us that development must mean more than simply economic growth. It requires the development of people and their capabilities, as well as environmental and socioeconomic policies that are sustainable in the long term. Social and gender inequalities must also be addressed. Health planning and practice is closely linked with these broader development goals. All too often policy making and planning to put PHC into practice have taken place at the central level, with little understanding of the problems and constraints on implementation in specific health districts and communities. Improving people’s health and their access to health care remains a major challenge.

Health Action plans to address the major questions raised by the need to have clear and practical guidelines to implement PHC. At a time of economic constraint, how can equity be achieved? How do we prioritize people who should pay for this? The journal will focus particularly on organization and management issues and the training of health personnel, with suggestions for more a rational use of resources.

For further information contact: Appropriate Health Resources & Technologies Action Group (AHRTAG), 1 London Bridge Street, London, SE1 9SG, UK.

International Society of Drug Bulletins holds first summer school

Regio Emilia, Italy, 22-26 June 1991

The aim of the summer school was to share the skills and experiences of different bulletins, to strengthen the ISDB network and to plan future training activities. ISDB members, currently representing well established bulletins in France, Germany, Italy, the Netherlands, Spain and Switzerland joined with colleagues from Africa, Asia, Latin America (supported by HAI-Europe and WHO/DAP) and Eastern Europe (supported by WHO/EURO), to discuss the philosophy, development and technical management of their publications.

There was absolutely no question that access to objective drug information was essential for rational prescribing, participants emphasized, and that drug bulletins could play an important role in this respect. And to fulfill this role drug bulletins should be independent, although it was recognized that in practical terms, all bulletins were “dependent” to some extent, whether on a government authority, funding or umbrella organization, or even their subscribers.

Suggestions for action

After plenary presentations and discussions participants had a choice of workshops to attend which covered every aspect of bulletin production from initial development, sources and assessment of material, independence of authors, financial management, production and distribution, informatics, and relations with health authorities, industry, international organizations, professional associations and readers.

Many ideas and proposals for action emerged during the discussions. These included:

- to compile a minimum information kit (books and journals) for new journals, which could be funded internationally;
- to set up a database containing the articles published by bulletins and the literature they cite;
- to start a CD-ROM based service for bulletins from developing countries or other young bulletins;
- to campaign for improved encourage bearings of bulletins of adverse drug reactions;
- to encourage the use of drug bulletins as teaching materials in medical schools and schools of pharmacy.

The next ISDB summer school is planned for July 1992 in Yokosuka, Japan, immediately prior to the triennial World Conference on Clinical Pharmacology, and is intended principally for participants from Asia and the Pacific.

For further details of ISDB activities and membership contact: Dr. A. Hershberger, Chairman, International Society of Drug Bulletins, 77 Catherwood Road, London W6 ODU, UK.

Action Programme to lead drug use research

N o country, even the most developed, has totally succeeded in improving the prescribing patterns of medical personnel or the use of drugs by the public. Many obstacles exist to the rational use of drugs, ranging from the lack of objective information to excessive demand by the patient, the prevalent belief that “every ill has a pill” and the attitudes of members of the medical profession. In such a complex issue, research has an important role to play and several international organizations, research groups, and networks are now actively involved in research activities, although their approach can be different.

In order to share experiences, to stimulate activities, and to discuss priorities and ways to better coordinate strategies, WHO’s Action Programme on Essential Drugs together with UNICEF organized a meeting on operational research relevant to the rational use of drugs. The meeting, hosted by the International Children’s Centre in Paris on 25-26 March 1991, was attended by representatives from selected developing countries (Bangladesh, Nepal, Bangladesh, Panama, The Philippines, Sri Lanka, Zambia), from international organizations (WHO, UNICEF, The World Bank) the French and Danish development agencies, academic institutions (University of Amsterdam, Karolinska Institute, Harvard University School of Public Health), and from existing networks such as DURGAFORO and INRUD.

The various organizations presented their approach to research in rational drug use and some of the research undertaken.

The country presentations focussed on problems faced in conducting research and practical experience gained. Methods of problem identification, priorities in research, and methodologies were then discussed in group work. Although consensus was not reached on all issues, there was a general recognition of the need of conducting problem-solving research aimed at developing solutions. Research should be country specific, concluded the participants, and be linked to the development of national pharmaceutical policies. Strengthening of already existing networks and better coordination and harmonization among the various activities also considered of major importance and the Action Programme was given a clear responsibility in developing, promoting, and coordinating future activities.
Drug Information Centre (DIC) network in Sweden

**Figure 2. A Drugline printout of the question on norfloxacin treatment in children, discussed in text.**

**Si:** DRUGLINE

**LO:** Hudinge

**ED:** 000068

**QD:** 000015

**QN:** 07307

**GN:** norfloxacin

**MI:** infant

**norfloxacin/THERAPEUTIC USE**

**norfloxacin/AVERSE EFFECTS**

**jardelux/ANTI-BACTERIAL**

**QT:** This question concerns an 8-month-old child with symptoms of pneumonia. The doctor wants to treat the child with norfloxacin. Is norfloxacin contraindicated in children?

**AT:** A question on norfloxacin treatment in children less than 12 years has earlier been answered by the drug information centre in Lund (1). It is concluded in this investigation that norfloxacin has caused ear lesions in animal studies. The common

**ciprofloxacin** has been reported to cause ear lesions in children in a growing child with cystic fibrosis (2). Developments in antituberculosis treatment have been reported after treatment with another quinolone (3).

**AG:** Documented experience of ciprofloxacin

**Review:** Search and information from available sources is evaluated. A preliminary telephone answer is given if urgently needed and a written answer is sent to the requester after internal review at a weekly staff meeting. In about half of the requests a search in the database Medline is performed and the answer is based on original articles when available. All answers are signed by the respondent and countersigned by a senior clinical pharmacologist, who takes full professional responsibility when the author is a junior doctor or a pharmacist. A standard form, together with a check list of literature sources, is used for documentation.

**The annual workload is around 500 consultations and to date more than 7000 questions have been answered and documented. The pattern of the consultations is shown in figure 1. Most of the questions concern adverse effects, including drug problems during pregnancy or breast feeding, and the majority of questions are asked about frequently used medicines. The number of questions from primary health care has increased from 1979 to 1980 and it is situated at the

**Drugline: An innovative database**

Experience over the years has shown that certain queries tend to be frequently posed and that answers to earlier consultations can therefore prove useful and save time. In order to benefit to the maximum from earlier work a database called Drugline has been created. This contains most of the questions answered by the Centre since 1982 and it is situated at the

**Karolinska Institute Library and Information Centre. The questions are indexed with key words according to the MESH vocabulary of the US National Library of Medicine (NLM) and the search technique is the same as for Medline. The database contains to date about 4600 documents and is updated monthly with an annual growth rate of some 500 entries. The language is mainly Swedish but 6% of the documents are in English as well as all key words and field descriptors. The use of Drugline has increased steadily since its introduction in 1984.**

**How is a question handled?**

**Question number 07307 was asked over the telephone in February 1999 by a paediatrician in the Hudinge Hospital. The question concerns an eight month old child with pseudomonas pneumonitis. The doctor wants to treat the child with norfloxacin and asks if this treatment is contraindicated in children.**

A search in the Drugline file reveals that a similar question was answered one year earlier by the DIC in the southern part of Sweden. A preliminary answer, based on this earlier question, is given over the telephone on the same day. In summary the doctor is told that documented experience of norfloxacin treatment in infants is lacking. Based on animal studies the risk of articular cartilage lesions caused by norfloxacin and related substances such as ciprofloxacin is pointed out. One case report of reversible arthritis in a patient with cystic fibrosis taking ciprofloxacin has been published. On strict indication norfloxacin is not considered contraindicated in children and in this specific case a careful risk-benefit evaluation has to be done. For further information personal consultation with a named clinical expert is recommended. A later follow-up reveals that the doctor decided to treat the patient with norfloxacin and that this decision was based on the consultations and the urgency of the case.

The earlier question was followed up by a complementary literature search including Medline, and a written answer was sent to the questioner two weeks later after discussion and authorization at the weekly staff meeting. The whole document, with the exception of patient and inquirer identities, was fed into Drugline in May and a printout is presented in figure 2. This example illustrates not only the working method but also the usefulness of establishing a DIC network which can access answers to similar questions dealt with somewhere else and made available in a jointly produced database. It also illustrates the role of a DIC as an intermediary to clinical experts.

A network of drug information centres, organized according to the Hudinge Centre model, is now developing in Sweden at the university hospitals (fig. 3). This is the result of cooperation between clinical pharmacologists and hospital pharmacists with sponsorship by the National Corporation of Swedish Pharmacies. In order to reduce duplication of

**Continued on Page 16**
LETTERS TO THE EDITOR

World Vision International adopts essential drugs policy

I want to congratulate you on the 20th anniversary of Essential Drugs Monitor issue. This is an excellent issue, which I thoroughly enjoyed reading and found very relevant. For your information, I am sending you a copy of the World Vision International’s Policy on Essential And Donated Drugs, which has come into effect since October 1990.

World Vision International has an official relationship with WHO. It has programmes in 53+ countries, runs 6,050 projects globally and has an annual budget of $210 million. Its $40 million Global Fund project last year included $20 million worth of pharmaceutical supplies. Because of our full support for the implementation of the WHO action programme on essential drugs policy, and concerned by the high percentage of unsuitable pharmaceutical donations, World Vision International has now adopted a policy on essential and donated drugs.

Our emphasis is on the use of essential drugs using WHO’s model list and national lists whenever they exist. Our experience is that much pressure is brought upon us by some suppliers to accept their short-dated and non-essential drugs. So far, WV has successfully stood its ground and plans to do so in the years to come.

Eric R. Ruan, Ph.D., Director, International Health, World Vision International, Calle de la Tourelle, CH-1299 Geneva, Switzerland. Congratulations to WV on its adoption of its essential drugs policy. Are there any other organisations among our readership which have recently adopted a similar policy? Do write and tell us how you are working towards a more rational drug supply. The Editor.

Instability of ampicillin suspensions

I read with interest the article entitled “WHO/UNICEF study on the stability of drugs during international transport” in EMD-11-91 and would like to pursue a similar study in India.

In addition to the loss during transport, I am also worried about the poor stability of drugs in a tropical country like India. We have investigated the stability of reconstituted ampicillin suspensions stored at room temperature. Unfortunately, we found that ampicillin suspensions are unstable and there was a progressive loss of potency (range 31.2% to 45.0% when stored at room temperature). These findings emphasise the need for caution in using stored ampicillin suspensions and the requirement for substitution with dispersive tablets.

Dr C. C. Adhikari, Associate Professor, Department of Pharmacology, Jawaharlal Institute of Postgraduate Medical Education and Research, Pondicherry 605006, India.


A model for other countries?

We think that this model of a drug information network system has the potential for international adoption and collaboration. Discussions are already taking place at several centres of clinical pharmacology in Europe to start a similar service. This could be further developed in collaboration with existing medical drug information centres, such as those in England and Sweden, with the aim of producing a European Drugline available online. Alternatively the possibility of using new communication technologies such as CD-ROM (compact disc read-only memory) for storage and distribution should be evaluated. This might be useful for solving communication problems where the telephone network is inadequate but where a PC is available, which is the situation in some developing countries.

There is no doubt that a need exists for problem-oriented drug information produced by independent experts within the health care system. Such a service can assist the prescribing physician to be more rational and efficient. Modern information technology provides a powerful tool, which we should take advantage of, to contribute to safe and effective pharmacotherapy.

References:

This is a well-written book by Dr Evan Chidemore of the Nigerian Federal Ministry of Health which provides detailed information of drug registration strategies applicable to developing countries, as well as specific registration details for the major nations of Africa. Additionally, it contains an excellent discussion of the need for and the formulation of national drug policies accompanied by short case studies of drug policy in Egypt, Mozambique, Mexico and Bangladesh.

Useful appendices include the basic elements of drug legislation and the WHO model list of essential drugs.

Unfortunately, the high price of the publication - US$79 - may put it beyond the reach of many potential readers. On the positive side, the publisher, under their Pharmacos-2000 programme, will send one copy at no charge to every college and school of pharmacy worldwide, an initiative which perhaps other publishing houses and organizations could consider emulating.

Available from: Interpharm Press, 1358 Beach Parkway, Buffalo Grove, IL 60089, USA. Price US$79.


This book provides a practical, step-by-step guide to the ways in which better planning and management can be used to improve the services of district health systems. Firmly rooted in practical experience, the book adopts a problem-oriented approach, stressing plans and actions that respond to everyday problems and fall within the reach of the district health team. The objective is to help managers and other personnel in developing countries anticipate problems, avoid common pitfalls, use the right planning tools, make wise choices, and keep ambitions in line with the realities of needs and resources. To this end, the book makes abundant use of practical examples, case histories, checklists and photographs to give concrete meaning to the advice provided. The book features nine chapters, focused on each of the main stages of the planning cycle, moving from analysis of the present situation to the implementation of specific measures and the monitoring of their effectiveness. The opening chapters show readers how to assess the existing district health system, identify its strengths and weaknesses, establish priorities, and set programme objectives and targets. Emphasis is placed on the use of simple techniques and simple tools to make complex problems more easily understood and managed.

Available in English (French and Spanish in preparation) from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: SwFr.19.–US$9.60, and in developing countries SwFr.8.–US$5.60.

Essential Drugs Monitor

PUBLISHED LATER

Price Indicator on International Low-price Sources for Essential Drugs, Medico International, 1991

Medico International is a non-profit medical relief organization cooperating with organizations in Africa, Asia and Latin America in the field of primary health care, including the supply of essential drugs. It is opposed to the production and marketing of dangerous, ineffective, inappropriate and harmful drugs.

This price indicator is an update of earlier editions and includes a selected choice of suppliers for generic drugs. It is based on WHO's Model List of Essential Drugs but, because of widespread use, a few products are included which are not on the WHO list.

It provides an indication of current generic drug prices on the international market - without assessment of the real costs of the drugs because of differences in financial terms, transport costs, delivery times, expiry dates, handling services, etc. It cannot be used to order products. To place orders suppliers should be contacted directly.

Available from: Medico International, attn. Leo Locker, Obermainalde 7, D-6000 Frankfurter FBG. Price: US$10 including mailing with a reduction of 25% for orders exceeding US$100. Single copies for institutions (NGO's or government) are free.


This book explores what can be done to move the widely-endorsed concept of community involvement in health from rhetoric to a functional reality. Noting that community involvement is often regarded as an expedient for gaining voluntary contributions of labour and resources, the book challenges health authorities and personnel to appreciate the magnitude of changes - from a shift in the fundamental goals of development projects to rethinking of the conventional provider-recipient model of health care - needed to establish the kind of partnership with communities that leads to sustained improvements in health.

Throughout, emphasis is placed on the distinction between merely seeking local support for a preconceived programme and the type of project that involves the people from the outset, empowers them to act as advocates for their own health needs, and thus creates a basis for continuing participation.

Available in English and French (Spanish in preparation) from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: SwFr.10.–US$9.60, and in developing countries SwFr.7.–US$6.60.


What is a reasonable price to pay for a pharmaceutical product? This can be a difficult question for drug managers to answer. Even after list prices are obtained, the manager may still not know the real costs of the products because of differences in financial terms, rates of exchange, shipping costs, handling services, delivery times, etc. In short, comparison among different vendors for the same product can be confusing.

The International Price Indicator Guide provides exactly what the name implies: an indication of generic drug prices on the international market. The guide is published annually and provides a spectrum of prices from non-profit drug vendors, based on their latest available catalogues or price lists. It is intended only as a reference and is not suitable for actually ordering products.

Available from: Management Sciences for Health, Drug Management Program, 165 Allandale Road, Boston, Ma 02130, USA.


This report addresses the pressing need for educational measures that can improve the competence and motivation of health personnel working in district health systems. Noting that personnel constitute the most valuable and expensive component of the health services, the report argues for the use of a systematic programme of continuing education geared to the functioning of a district health system, as a measure that can help staff at all levels improve their performance and maintain a high level of job satisfaction. Emphasis is placed on the importance of on-the-job training as an approach that encourages learning based on real problems and appropriate to real needs in the community.

Throughout the report, brief case studies are used to show how different countries have made continuing education an integral part of district health management.

The report opens with a discussion of the ways in which continuing education can strengthen the district health system and thus support its role in ensuring universal access to primary health care. The second section lists operational principles for the management of district health systems and shows how specific managerial functions are facilitated when health staff are continuously encouraged to improve their skills and competence.

Factors that can influence the successful operation of programmes for continuing education are identified in the third and most extensive section, which considers the importance of political and financial commitment, the choice of educational methods, the relevance of learning materials, the professional aspirations of staff, and methods of supervision.

Factors to consider when evaluating the success of a continuing education system are also clearly explained.

The final section presents and discusses six fundamental questions that can help authorities decide whether to include in a continuing education system and how it should be organized and managed. Data is drawn from a discussion of the merits of different forms of incentives to a list of reasons why some continuing education programmes have failed.

Available in English (French and Spanish in preparation) from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price SwFr.9.8.–US$5.40, and in developing countries SwFr.5.5.–US$3.30.
Essential Drugs Monitor

PUBLISHED LATELY


A practical guide to all aspects related to the provision of drug donations, covering the responsibilities of both the supplier and receiver. The book presents a number of case studies which provide examples of current practice and how this can be improved. It also highlights the complementary need for pharmaceutical information which is scarce in most countries where are beneficiaries of drug donations. Finally the book includes an overview of essential drug policies and special needs in emergency situations.

Available in French only from: PIMED, 24 quai de la Loire, Paris 75019, France.


This is the third in WHO’s series of model prescribing information, which is produced to assist national authorities, particularly in developing countries, when preparing drug formularies, data sheets, and teaching materials. This volume covers some 13 essential drugs used for the prevention and treatment of tuberculosis, for the treatment of leprosy, and for the treatment of diseases caused by nontuberculous mycobacteria, including localized cutaneous lesions, pulmonary disease, lymphadenitis and disseminated disease.

Model prescribing information is presented in three main chapters. The first, devoted to tuberculosis, opens with a detailed overview of the disease, its clinical features, and the main principles of prevention, bacterioscopy, and chemotherapy. The special problems of diagnosis and treatment of HIV-infected patients are briefly discussed. Readers are also given detailed information on the properties of antituberculosis drugs, preferred treatment regimens, monitoring of patient compliance and therapeutic response, and the treatment of relapsing and unresponsive disease.

Against this background, model prescribing information is presented for 10 drugs used in vaccination, chemoprophylaxis, and chemotherapy. Each drug is profiled in terms of its clinical uses, dosage and mode of administration, contraindications and precautions, use in pregnancy, adverse effects, and possible interactions with other drugs.

Drugs used in the treatment of leprosy are covered in the second chapter, which also features background information on the disease and the main principles of multi-drug therapy. The final chapter provides prescribing information for drugs used to treat non-tuberculous mycobacterial infections.


A collection of studies undertaken from 1985-89, which take an exploratory look at various aspects of drug utilization in Sri Lanka, gathering data with the help of disciplines such as pharmacology, epidemiology and anthropology. The author, who has a biomedical background, emphasizes the benefits of a multidisciplinary approach in examining the complex issues involved in drug utilization.

The study concludes that although policies for the improvement of drug use in developing countries are being initiated, the cultural complexity of drug use is poorly understood. Community involvement and self-help, cornerstones in the primary health care concept, can be threatened by a system very dependent on drugs, a technology which comes from outside and represents macrostructures. What an individual level seems to be a most well-functioning system, with positive pharmacological and symbolic effects, may in fact prove to be dangerous to the development of sustainable primary health care and an ecologically sound and self-reliant system. The author stresses that a critical focus on the micro-level leads to a new perspective on the macro-level and vice versa.

Available from: Department of International Health Care Research (IHCAR), Department of Clinical Pharmacology, Huddinge University Hospital, Karolinska Institute, Stockholm, Sweden

SELECTED ANNOTATED BIBLIOGRAPHY ON ESSENTIAL DRUGS


This is a critical guide to some 900 drugs in an estimated 2000 dosage forms which it describes as of doubtful efficacy, or a high-risk/benefit ratio, or which offer no benefit. These drugs represent nearly 25% of the registered drugs in the country. Many have either been banned, withdrawn, severely restricted or not approved for marketing in several countries, the author says. Overall, they constitute more than 50% of the total drug sales in Pakistan.

The author calls for the implementation by the Government of an essential drugs policy. An important first initiative should be to review the existing list of registered drugs in Pakistan, and form a national committee with the authority to enter withdrawal of all ineffective, unsafe and illegal preparations. A next step should be government-produced independent sources of information about drugs - such as a bulletin and a formulary. The quality of information provided by the drug industry should also be monitored, he says, citing a recent survey which found that 95% of participating physicians in Karachi said that pharmaceutical company representatives were their main source of information about drugs. The same survey found that industry promotional material in Pakistan provides limited, incomplete and misleading information and adds to irrational drug use.


In many countries economic development has clearly contributed to improving the quality of life and the health status of the population. However, there is growing concern that certain development strategies may in fact have adverse consequences for the health of particular population groups. These problems are being increasingly recognised by government ministries and international agencies, but additional research is needed to identify the changes in policy that could reduce the health risks arising from development and contribute to improving health.

This publication reviews the literature on the links between health conditions and development policies in five sectors: macroeconomics, agriculture, industry, energy and housing. It identifies the immediate and underlying causes of ill-health in each sector and pinpoints major gaps in existing studies. In so doing, it provides a basis for future studies to examine linkages across sectors, assess sectoral connections that heighten health risks, and identify important areas for policy intervention.

Available in English only from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.31. and in developing countries Sw.fr.21.70.
Essential Drugs Monitor

PUBLISHED LATESTLY


The European Community exports 2.4 million ECU worth of pharmaceuticals to the Third World. An unknown proportion of these products are not approved or have been banned for safety reasons in one or more EC countries. Double standards enable the European pharmaceutical industry to market obsolete pharmaceuticals in Third World countries when their use is banned domestically, states the author of this report.

The publication gives the results of a survey of drugs, banned or withdrawn in one or more EC countries, which were for sale in Africa, the Caribbean, the Middle East or Asia in 1988. National guides with prescription information (the so-called MIMS guides) were used as a reference for products of EC-based companies on the market in 48 countries. More than 75 products are listed. Widely used pain-kills from the largest category. The list also includes several dangerous antibiotics and irrational combination products.

The report also describes European export legislation and discusses the recent history of initiatives in the European Parliament to restrict exports of unsafe drugs. The authors make recommendations to improve export standards, including stricter export legislation, full disclosure of information, adequate standards for registration of drugs within Europe and public access to information on the criteria for approval of drugs.

Available from: WEMOS/Pharma Project, PO Box 40066, 1009 BB Amsterdam, The Netherlands. Price: DJ$16.00 for individuals and non-profit institutions or DJ$30.00 for others, plus postage DJ$3.00 Europe; other countries DJ$7 (surface mail) or DJ$7.70 (airmail).


This book describes the role of pharmaceuticals in self-care in two urban poor communities in Metro Manila, one with a community-based health programme and one without. The people’s ideas about drug use, including concepts of illness causation, drug efficacy, and criteria for choice of therapy, are analysed. The micro-level is then related to a broader context of the pharmaceutical environment at the community and at the national levels including mass promotion of drugs in the mass media, the presence of dole-out programmes giving free drugs and the availability of a range of medicines in community stores.

The Philippines’ National Drug Policy is described and assessed in relation to problems found in the communities. Attempts of non-governmental organizations to rationalize drug use are evaluated, with careful warnings on the limitations of ‘alternatives’ such as the production of medicinal plants.

The study utilized participatory research methods, from the use of health calendars and role-playing. Suggestions for community-based research, with constant feedback to communities through appropriate educational materials, have also been included.

Available from: Health Action Information Network, 9 Cabbabnan Road, Philden Homes, Quezon City, Philippines. Price: local orders, DJ$10 each postpaid; foreign orders, US$13 postpaid for Third World countries; US$25 postpaid for developed countries.


With the rising cost of medical care coupled with a slowdown in the growth of the Western economy, the money spent on prescribed drugs has become a matter of violent controversy. The need for economy in health care is clear, but what is contested is the extent to which it is wise to attempt to save expenditure on drugs rather than on other services. If the flow of money is reduced, will this put patient care at risk? Will the research effort or the return on investment in the pharmaceutical industry be endangered? Other questions concern the way in which money can be saved; how can wastage be reduced.

From 1984 onwards, a team set up by the World Health Organization’s European Office and its Collaborating Centre at the University of Groningen has been undertaking regular studies of these issues, designed to provide policy makers, industry and all those involved in patient care with an objective analysis. Much of the information is distilled from the many attempts which have been made in various countries to control pharmaceutical expenditure - sometimes successfully, yet more often to no effect and sometimes doing more harm than good. The present sixth edition of “Drugs and Money” provides a compact and updated guide to this important subject.


Bibliography on Drug Utilization, INRUD, 1991

This is a comprehensive, abstracted bibliography on drug utilization, factors influencing patient and provider drug use behaviour, and interventions to improve drug use patterns that have been attempted. The bibliography is regularly updated and currently contains over 1,000 references. It is also available in database form, which requires Reference Manager Version 5.0 software, or in printed Medline format.

Available from: International Network for Rational Use of Drugs, 165 Allendale Road, Boston, Massachusetts 02130, USA. Price: covered by US$10 to cover cost of reproduction.

The Provision and Use of Drugs in Developing Countries, A. Harden, S. van de Geese, H. Geerling and A. Le Grand, HAI, 1991

A comprehensive review and annotated bibliography of over 200 studies on the use and prescription of drugs in developing countries, with a focus on self-medication, prescribing practices and local distribution of drugs.

The bibliography aims to bridge the gap between drug use researchers and policy makers. It includes a section on research methods for health workers, policy makers or consumers who wish to carry out their own research. Conclusions with direct implications for policy are stressed in the abstracts. The review summarizes these conclusions and makes suggestions for changes which are needed such as:

- More objective information for prescribers and consumers;
- Strict controls on advertising;
- Attention to traditional cultural beliefs affecting medicine use;
- Essential drugs lists which limit the number of drugs on the market to those that are safe, effective, affordable and needed;
- Research on the public health consequences of irrational drug use, on the impact of essential drugs policies and on people’s perceptions of their needs.

Available from: Health Action International- Europe, J. van Lenneplaats 3347, 1083 SJ Amsterdam, The Netherlands. Price DJ$5.50 + 10% handling charges. A limited number of copies are available free of charge to libraries and researchers in developing countries.


A well written and clear in-service training manual which provides comprehensive instructions on medical stores organization, storehouse management and workers’ responsibilities and grievances procedures. The book contains many graphic illustrations of the operations described and is enlivened by excellent cartoons which alone will guarantee that it is not left to gather dust on a shelf. The guide is particularly notable for an excellent section covering human relations at work, conflict resolution, and particular problems which may be faced by women in the workplace, such as sexual harassment.


This manual, which is complementary to WHO’s 1986 publication, Basic Tests for Pharmaceutical Substances, describes simple and readily applicable tests for verifying the identity of 150 pharmaceutical dosage forms in common use. The methods described use a limited number of easily available reagents and equipment, and do not require a fully equipped laboratory. They need not be carried out by a qualified pharmacist, but should be performed by persons with some understanding of analytical chemistry. Basic tests are not intended to replace the requirements of pharmacopoeial monographs, which give an assurance of quality, as opposed to merely confirming identity.


Important
This Action Programme cannot supply the publications on these pages. Please write to the address given at the end of each item.

"No thanks, Nora... I'll just take 3 million pounds." ref: The Health Conscience with kind permission of Dr. J. Gill.
PUBLIC EDUCATION

Don't take drugs lightly, French consumers warned

Remarkable progress has been made in recent decades in drug efficacy to state the organizers of a new French campaign to improve the use of medicines by consumers. But:

The French are heavy consumers of drugs

Recent research shows that the French consume twice as many drugs as the Germans and three times as many as the Americans. Each French person buys an average of 50 packs of drugs a year, indicating a pattern of over-consumption, which in 1886 led to 17,200 hospital admissions due to pharmaceutical poisoning. According to a 1998 survey by the Société française d'Education pour la santé, 81% of French adults take at least one medicine a year.

As others, such as antibiotics, may be regarded as "dangerous", leading to patients halting their treatment too early.

Such beliefs, state the campaign organizers, lead to irrational behaviour such as:
- increasing the dose to make the treatment "more effective";
- making a personal "selection" of items on a prescription;
- indiscriminate use of items in the family medicine cupboard;
- taking a drug that was prescribed for a different purpose;
- passing the drug on to someone else;
- mixing treatments; and taking a second drug to offset the effects of the first (e.g. a stimulant after a sedative).

Using drugs in this way - because they are taken too much for granted - reduces or even destroys their therapeutic efficacy and leads to adverse effects ranging from minor functional disorders (skin rashes, digestive and liver complaints, behavioural disorders) to major cardiac disorders.

Campaign for better drug use

In order to promote more knowledgeable and discriminating consumer attitudes and behaviour a major public education campaign has been jointly launched by France's Ministry of Social Affairs and Solidarity, the National Health Insurance Fund and the French Committee for Health Education.

The campaign, targeted at all consumers, is aimed at making people aware of the realities of drugs: that every drug contains active substances which can become dangerous; that these substances, in scientifically calculated amounts, are what make it effective, but that if the drug is wrongly used they can produce adverse effects on health. The goal is to put the therapeutic role of drugs into a broader perspective, which includes advice, healthy living and good communication between patient and prescriber.

Disseminating the message

The central message of the campaign is: "A drug is not something to be taken lightly" is being diffused through a variety of media, including a 30 second television spot, direct information to all doctors and pharmacists, and inserts in professional journals. Health professionals who wish to pass on the campaign message to their patients and clients will have a number of information materials at their disposal such as:
- a small poster (see illustration) for the waiting room of private or hospital practitioners and a small poster for pharmacies; these posters advise patients on the rational use of drugs and urge them to engage in dialogue with their doctor and pharmacist;
- a leaflet containing general information on the use of drugs available to patients from doctors and pharmacists.

Using local networks

Decentralizing the campaign is a key approach to bringing about far-reaching and lasting changes in each individual's behaviour with drugs. The networks of each of the three campaign organizers are being called upon to pass on and boost the campaign message at the local level. Steering committees at regional and departmental levels are responsible for organizing and implementing information and awareness activities directed at local target groups such as health professionals, press clubs, companies, secondary schools and universities.

Media response

The French media, while welcoming the campaign, has pointed out that the problem extends beyond the misuse of drugs by the general public. "Le Monde" observed that the campaign was directed primarily at consumers and not at the prescribers - pharmacists, physicians and others. It commented: "Yet these people are just as much involved in the phenomenon of over-consumption; for instance, the number of products written on the average prescription is on average much higher than in other countries... Without doubt this is one of the major causes of the high consumption of drugs; that is why doctors ought to learn - or be re-taught - not to prescribe a drug systematically the moment a patient appears with a complaint. Very often what patients come for when they go to the doctor is to be relieved of some fear. In other words, what is needed is a dialogue rather than a technical response based on drug prescription."