Common Andean drug policy

Although the Andean states were among the first to direct public policy towards strategies for more rational drug procurement and use, drugs remain in short supply to many of the population. Procurement costs are often needlessly high, and knowledge of appropriate drug use remains unacceptably low for both prescribers and consumers. The difficult economic situation in Latin America, diminished funding in the public sector, and the trend towards liberalization of the import market further complicate the pharmaceutical sector.

In recent years the Andean group has been systematically developing common strategies and instruments to tackle many of these shared concerns. This work has included such issues as harmonized systems of drug registration and quality control, common essential drugs lists and pharmacological standards, and technical criteria for a common Andean drug market.

In May of this year, senior policy makers and health officials from all five Andean countries—Bolivia, Colombia, Ecuador, Peru and Venezuela—met to consolidate this earlier work into a common pharmaceutical policy. The aim is to create a sub-regional framework for sustainable rationalization of the pharmaceutical sector in the light of present realities, constraints and opportunities. The new policy (see page 13) covers such areas as legislation, selection, quality assurance, supply, financing, rational use and a common pharmaceutical market.

The policy declares, with no ambiguity, that the role of the state in the pharmaceutical sector, whatever the political ideology, is to guarantee availability and equal access by the entire population to effective, good quality drugs at affordable prices, and to ensure their proper use. It emphasizes that the availability and accessibility of drugs are parameters for measuring the quality of the health services, and constitute social indicators of justice and equity.

Citing the far reaching process of change under way in the public sector, the policy emphasizes that ensuring availability and access is a function that cannot be delegated, although it can be implemented by very different mechanisms and with various forms of participation by the private sector. This is an important message at a time when the role of the public sector is changing in many countries and commitment to the free market economies and decentralization of control are the leitmotif of the nineties.

At the core of the policy is a commitment to the public health benefits of the essential drugs concept, and the economic benefits of generic drugs (most essential drugs, of course, are available in generic form). Explaining the rationale of this fundamental approach, the policy states that the selection of essential drugs—those that are the most useful to deal with the majority of health problems—cuts down the number of products to be manufactured, promoted and marketed, thus making it easier for health professionals and patients to become familiar with them. Their mandatory use in the public sector and their value for the private sector, facilitate the processes of selection, purchasing, storage and distribution, and especially their rational use. Generic drugs, by permitting identification of the product by its scientific name, make it easier for the prescriber, dispenser and user to choose between many alternatives competing in terms of quality, price or convenience. They introduce competition and transparency into a market.

The policy points to the fact that drugs cannot be treated just like any other merchandise. The drug market is susceptible to distortion. It is also unique in that prescription drugs are not selected by the consumer, who has little or no basis on which to evaluate their value. Prescribing and use are influenced by strong commercial promotion, and many health professionals and patients lose sight of the fact that drugs can only have relative and not absolute safety.

The common Andean policy is an important step towards regional cooperation and rationalization of national drug policies.
NEWSDESK

Award for Pakistani paediatrician

Professor Tariq Iqbal Bhatta has received the 1993 Olle Hanson Award in recognition of his outstanding work to promote the rational use of medicines.

Professor Bhatta has led campaigns in Pakistan against inappropriate promotion and prescription of paediatric medicines. In particular he has focused attention on the dangers of giving children antimicrobial drugs, for example, and the unethical marketing of these products.

In 1990 Professor Bhatta brought world attention to the fact that infants in his hospital were dying as a result of bowel paralysis caused by paediatric preparations of the antimicrobial heparin. As a result of his campaign the manufacturer withdrew these preparations worldwide and many countries took regulatory measures to restrict the use of antimicrobial drugs.

* The award is presented annually in memory of Olle Hanson, a leading Swedish paediatrician, who led a campaign for the withdrawal of clofibrate.

He also led a long battle to obtain compensation for the many people who were injured by the drug.

Patients’ charter for Malaysia

Malaysia has become the second country in Asia, after South Korea, to draw up a Patients' Charter, so recognising essential health care as a basic human right. The document outlines the rights of anyone seeking medical services in the public or private sector and also requires patients to exercise their rights reasonably, reports the April issue of HAI News.

Signed on 1 March 1993, by all the main medical groups in the country and the Federation of Malaysian Consumer Associations, the Charter aims to redress grievances, participation, representation, health education, a healthy environment and accurate information.

The right to information, as defined by the Charter, includes the right to advice on all aspects of medicine, prescription and purchased medicines, as well as drug efficacy and safety. Patients need to know the dosage to be consumed and frequency of consumption. They should also be told the purpose for which the medicine is being prescribed, and its possible side effects. Information should be given on food and drugs to avoid when taking a medicine, and measures to be taken if a dose is forgotten or in case of an overdose.

Dr Sothi Rachagan the main author of the Charter summed up its underlying philosophy saying, “There will be those who assert that patients should concentrate on getting better and that doctors should concentrate on making them better. Neither should focus on rights. The argument is that patients have needs not rights. The fact is that they have both.”

Light can damage some vaccines

Is your vaccine stored in the dark? If it is a measles or BCG vaccine then it should be. Both of these vaccines are sensitive not only to heat but also to light. This is particularly true once the vaccine has been reconstituted. Most, but not all, manufacturers provide their vaccines in amber vials or ampoules. Some manufacturers also provide a convenient light shield as a further protection.

If the measles or BCG vaccine that you are using is not protected against light by the manufacturer, or if the vaccine is transferred to another container during reconstitution, it should be stored below 8°C and kept in the dark.

Spain: collaboration on new prescribing guidelines and improving drug information

A new prescribing guide for primary health care centres is being drawn up as part of a collaboration agreement between the Health Ministry and four doctors' associations, reports Scrip No. 1828. The guide will contain transparency sheets for about 350 widely used products, giving a “critical evaluation” of each active ingredient. It will also list the generic name; brand names; product presentations; treatment cost for defined daily doses; pharmacological; pharmacokinetic information; therapeutic indications; dosage; means of administration; adverse reactions, interactions, precautions and contra-indications; and instructions for use. Comparisons will be drawn between different products “when it is considered useful and didactic,” according to the agreement.

Three other projects will be carried out this year by the four primary health care associations involved in the collaboration agreement, which is aimed at improving drug information and training for doctors.

The Spanish Society of Rural and General Medicine will be responsible for drawing up transparency sheets for new drugs launched between January 1993 and July 1993 (excluding hospital-use products). These will analyse the benefits of each active ingredient, taking into account available alternatives.

The Spanish Society of General Medicine will draw up diagnosis and prescribing guidelines for common diseases in adults. They will look in particular at acute respiratory infections, arterial hypertension, degenerative diseases and osteoporosis, hypercholesterolaemia, diabetes and asthma. The guidelines will include a basic clinical description of each disease, diagnostic criteria, information which should be given to the patient, usual treatment and any follow-up action to be taken by the patient. Short information sheets will be drawn up for the patients.

The Spanish Paediatric Association will draw up therapeutic protocols for paediatric illnesses, namely respiratory infections, asthma, acute gastroenteritis, urinary infections, constipation and fever.

Each of the projects will be assessed by the Health Ministry's Rational Drug Use Committee. The Health Ministry will provide funding of Pta21.2 million ($171000), and distribute the transparency sheets, prescription forms and free to doctors working in the national health service.
Essential Drugs Monitor

NEWSDESK

Twenty-two tons of expired drugs

I n Sarajevo, where hospitals are short of everything, to the point that doctors have sometimes to sterilize compresses for reuse, tons of antibiotics and other drugs are waiting to be incinerated. Moved by the desperate plight of the city’s inhabitants, many individuals and companies have donated drugs, but these are frequently so ancient that they would be more harmful than curative.

These expired drugs take up precious space, that could have been used for essential items, in convoys of humanitarian aid. They cost money to transport and to destroy.

The main hospital in Sarajevo estimates that it has received twenty-two tons of expired drugs that now has somehow to dispose of. "We sometimes have the impression that certain companies just dump the expired contents of their warehouses on us," says one hospital pharmacist. "For instance, we received the contents of 12,000 boxes of one antibiotic which had expired 14 years ago! And that wasn’t all. 8,600 tubes of antibiotic ointment which we were sure had expired in 1984 and 1986."

The situation is such that the Bosnian Government has had to insist on the presence of pharmacists in the UN logistic centres to intercept parcels of unsalable products and to determine delivery priorities.


Inappropriate drug donations in times of emergency cost precious time and money.

MaLAM Australia established

T he Australian Government Pharmaceutical Benefits Scheme Education Programme has awarded MaLAM $123,000 to establish MaLAM Australia. MaLAM’s new subsidiary will focus on pharmaceutical marketing in Australia using similar techniques to those developed by MaLAM International over the past decade. Topics for MaLAM Australia letters will be chosen by an advisory board chaired by a pharmacologist and epidemiologist, Dr John Marley. The MaLAM Australia Advisory Board includes representatives of the Australian Medical Association, the Royal Australian College of General Practitioners, the Australian Nurses Federation, the Pharmaceutical Society of Australia and the Society of Hospital Pharmacists of Australia. Priority will be given to advertising claims according to capacity for harm and "distance" from scientific literature.

MaLAM’s new logo

MaLAM has decided on its new logo, which is to contain three symbols: a globe, a pen and a serpent. The globe signifies MaLAM’s international scope, with subscribers in over 50 countries and distributors in Australia, Canada, France, India, New Zealand, Sri Lanka and the United Kingdom. The pen is the symbol of lobbying and the serpent is an internationally recognised sign of medicine.

FDA acts against misleading marketing of osalazine

T he US Food and Drug Administration (FDA) has announced that Kabi Pharmacia will be required to undertake an extensive campaign to correct misleading promotion and advertising for its ulcerative colitis drug osalazine.

The FDA approved osalazine in July 1990, to maintain periods of remission of ulcerative colitis in adults unable to tolerate sulfasalazine. In its press release of 2 August, the FDA announced that after a year of investigation it had found that the company had illegally promoted osalazine for the treatment of mild, moderate and severe ulcerative colitis; for use in children; and as a "first choice" therapy in the treatment of ulcerative colitis.

In a consent decree signed by Kabi Pharmacia and the FDA, the US District Court in New Jersey entered a permanent injunction against the company with regard to the marketing of osalazine. Under the terms of the decree, it has to revise all future advertising and promotional materials for the drug and for one year these must have FDA clearance. It also has to destroy all existing promotional materials.

Kabi Pharmacia must also provide an FDA-approved corrective training programme for all sales, marketing, regulatory and legal staff. The company has to run a six-month corrective advertising campaign which will include remedial advertisements in medical journals and letters to all physicians contacted about osalazine by the company’s sales force. Finally, the company has to pay $US85,000 to the FDA to cover the cost of its investigation and set up a $US300,000 escrow account to pay for the corrective campaign and to reimburse the FDA for its oversight.

Commenting on the case the FDA Commissioner, Dr David Kessler, said: "Some have argued that the goal of drug promotion is to educate physicians. In this case the company’s goal was to increase sales at the expense of patient care. Promotion that is not aimed at the proper treatment of patients is one of the factors contributing to the rising costs of health care in this country, and we all need to address that issue head-on", he added.

Comecor “clean-up” in Brazil

T he Brazilian Health Ministry has set up a drug assessment committee (Comecor) to "clean up" the pharmaceutical market, and to evaluate reports issued by the Health Monitoring Secretariat (SNVS) on new drug approvals.

The move follows serious problems at the SNVS - drugs have reportedly been approved with incomplete efficacy data, more than 30,000 registrations have disappeared from Health Ministry computers, some products were withdrawn without official notification, and many products are said to have been relaunched with a different active ingredient under the same brand name (Script No. 1799).

The committee includes representatives from the Society for the Surveillance of Medicines, Sobarovime, the Brazilian Medical Association, the Society for the Progress of Science (SBPC), the Consumers’ Association, the Pharmacology and Experimental Therapeutics Society, the National Academy of Medicine, the Federal Pharmacy Council, and the Pharmacists’ Association.

Professor Elísio Carlini, president of Sobarovime and a member of Comecor, commented to Script that the committee was "trying to put some order into the medicines jungle". It has already carried out a study on hepatoprotectives and is planning further studies on ophthalmological, weight loss and memory products. Of the 88 hepatoprotectives evaluated, 95% were found to be therapeutically ineffective and 5% of dubious therapeutic value. Companies have been given 30 days in which to prove the claims made in the product labelling, and if they cannot, the products will be suspended.

The committee will also be looking at inappropriate drug combinations - many products on the Brazilian market contain three, four, or five substances, Professor Carlini commented. Health Ministry statistics show that over 60% of medicines contain more than one active ingredient.

Comecor’s work could result in a large number of suspensions according to Professor Carlini, who believes that about half of the medicines on the market - many of which are copy products - should be withdrawn. The number of products available in Brazil and their indications is a "mystery" to the Health Ministry, although estimates suggest that 40,000 medicines have been registered, and 10,000 products in 20,000 - 25,000 presentations launched. Professor Carlini commented. The health authorities are now trying to set up a national drug database, but its lack of resources and trained staff is making this difficult, he said.

Comecor has also expressed concern about the number of ethical products which are sold over the counter without a prescription, which Professor Carlini estimates account for 60-70% of Brazilian drug sales.

River blindness: NGOs agree Africa strategy in Geneva

The proposal to establish a World Bank trust fund that would make grants for controlling river blindness through ivermectin distribution in endemic African countries, dominated the deliberations of the second meeting of the Non-government Organization (NGO) Coordination Group for ivermectin distribution, held at WHO in Geneva in June.

The Group unanimously endorsed this suggestion and subsequently put forward proposals to the Bank on the possible structure of a trust fund. Central to its recommendations was that the fund should only be available to countries with national plans for controlling river blindness. While these plans should originate from ministries of health, NGOs should be involved at all stages, from drafting to implementation.

The Group urged that ivermectin programmes be used to strengthen primary care services where these are functional and where this is not the case they should be used as an entry point for primary health care. Health workers assigned to the programme should also be trained in the delivery of basic health services.

The Coordination Group is also preparing a procedures manual for the creation of national onchocerciasis control plans intended to assist programme planners to develop detailed guidelines for programmes eligible to be funded through the potential trust fund. The manual will address elements of ivermectin distribution programmes such as organization, health education and training, epidemiology, monitoring and evaluation.

The focus on the World Bank as a potential source of funds stems from its long-term role in the Onchocerciasis Control Programme (OCP) in West Africa, launched in 1974 and covering 11 West African countries. OCP’s control strategy is to spray rivers and streams with larvicide where the vector of the parasite, a small black-fly breeds. Donor nations and United Nations agencies through a World Bank OCP fund have provided $340 million since 1974 and when the programme ends by the year 2000, $580 million will have been spent.

According to a recent World Bank development essay, by 1995-96, 50 million people had been protected from the disease with an estimated 150,000 saved from going blind. Twenty five million hectares of arable land have been restored to production by removing the fear of living close to rivers associated with going blind.

Even with this extensive coverage, an additional 55 million people remain at risk in the 16 countries not covered under OCP. Distribution of ivermectin offers a new approach to protecting this huge population from the disease.

The Coordination Group will first focus its efforts on working with governments in Nigeria and Cameroon in finalising national plans. Here substantial progress has already been made and several NGOs are already distributing the drug. The Group has extended an invitation to other NGOs, particularly those working in the endemic countries, to join in the effort of ivermectin distribution to control onchocerciasis in these countries. Further information can be obtained from the WHO Programme for Prevention of Blindness which acts as the Coordination Group Secretariat.

For more information contact: Gorée, 180 ave H. Rouvier no. 8, 92200 Bagneux, France.

Gorée: special issue on essential drugs

The April/May edition of Gorée, a French language publication of the World African Association is devoted to French NGOs and their involvement in promoting the essential drugs concept in Africa.

This issue describes the work of organizations such as the Association for Ethical Medical Information and Development (APIDMED), the Association des Médecins de Première Assistance (AMPA), and the Association des Médecins de Première Assistance (AMPA). It also includes an article about WHO’s Action Programme on Basic Drugs.

Gorée is published in association with African Alternatives (ALAF), a quarterly review on African affairs, and gives details of forthcoming events which may be of interest to the readers of both journals.

In particular, this issue preview an ALAF organized conference to be held from 7-12 February 1994, which aims to bring together young people from all over Africa with representatives from international organizations, educators, researchers and nongovernmental organizations working on the continent. Topics covered at this conference will range from health and education to economic, technological and environmental concerns.

Move to develop medical journalism in Bangladesh

A national workshop in Bangladesh has reviewed the role of the mass media in consumer health issues, drug education and the rational use of drugs. Participants stressed the need to form a medical information group and to hold regular briefing sessions for journalists. They called for a ban on the use of non-scientific drug advertising, to ensure that prescribers and consumers receive objective information.

Other recommendations included a call for legislation to stop unregistered doctors prescribing harmful drugs and to prevent doctors regarding prescriptions as a means of making money.

Zimbabwe: new drug bulletin

Health workers in Zimbabwe have a new forum for exchanging news and information on drug related matters.

In July the first issue of the bi-monthly Zimbabwe Pharmaceutical News, the newsletter of the Government Medical Stores, was published with the backing of the Zimbabwe Essential Drugs Action Programme. It focus on five main areas: rational drug use; supply and distribution; staff training and development; changes in government health policy; and the role of the private sector in drug and medical supplies. One feature of the journal is a "swap shop" where health units with excess stock can offer it for exchange. There will be a strong emphasis on articles and letters written by health workers themselves to ensure that the journal reflects their current concerns.
Meeting tackles parallel drug markets

While drugs find their way into outlets which operate outside the legally authorized distribution network, their misuse can have serious public health consequences. These distribution networks of narcotic drugs and psychotropic substances are often referred to as the "parallel distribution system" and the sale of such drugs is known as the "parallel market". Although their existence is not new, it is only recently that these very profitable drug markets have started to be investigated. In order to reach a better understanding of the problems involved and to work out practical ways to reduce them, the United Nations International Drug Control Programme (UNDCP) and WHO organized a joint consultative meeting in Vienna from 16-18 June attended by 14 representatives, mainly from developing countries.

Background

The meeting heard that there are three main sources of supply to parallel markets: diversions from legal sources; illegal manufacture of legal drugs; and counterfeit production. In some countries illegal drugs find their way onto the parallel markets through official channels, such as hospital pharmacies or approved wholesale and retail dealers. In others, agents direct transshipments using countries with lax controls. In some places donated drugs are not necessarily subjected to close supervision, so facilitating their diversion to the parallel markets and reexportation of non-essential drugs as a revenue earning measure through import taxes can also add to the problem.

Poor drug distribution systems

Participants discussed how an inadequate drug distribution infrastructure can cause people to turn to alternative methods of drug supply. The lack of access to essential drugs continues to be a critical problem in some countries, particularly in rural areas, and the relatively high cost of drugs from legal outlets is another aggravating factor. Pre-packaged goods are often sold in quantities the patient cannot afford, so in this situation parallel markets offer a financial advantage by selling smaller quantities. Another factor is that whereas health centres frequently suffer from staff shortages, drug vendors are centrally located, with convenient working hours and no formalities involved in consulting or "dispensing". As participants shared their experiences it became apparent that in some countries the parallel market is integrated into socio-cultural systems with licit and illicit drugs being sold in pharmacies and by traditional healers. In others the trade is of a more random nature operated by street hucksters, general traders and medical personnel.

Faced with these serious concerns the meeting made the following wide-ranging recommendations:

At the international level

All drug importing and exporting countries should accept international drug treaties and implement their controls on international trade. WHO and UNDCP should provide governments with simplified guidelines on implementation and also train officials from all appropriate bodies. WHO and UNDCP should assist in developing action plans which take account of socio-cultural factors affecting parallel markets.

They should also support governments in assessing the medical and scientific needs for psychotropic substances and improving inspection programmes. WHO should prepare a model prescribing information for such substances.

Closer liaison between countries should be encouraged to devise successful national strategies for dealing with parallel markets. Concerned international agencies should consider establishing a data base on diversion and counterfeit drug trafficking. WHO and UNDCP should promote the use of information technology to facilitate regulation.

At the national level

Government backing at the highest level has to be mobilised if parallel markets are to be phased out. National health plans and drug policies should recognise existing parallel markets and develop and resource strategies to deal with them.

Research should be done to investigate the extent to which such markets operate, the types of drugs available and their sources. Health care, social and educational needs assessment surveys should be carried out in areas where a parallel market exists, and action taken as a result. For example, mobile pharmacy units could be sent to small communities, so that their access to legal drugs can be improved. Incentive payments and other benefits could be offered to pharmacies in areas where the parallel market is known to operate.

Several other recommendations were made for dealing with existing parallel markets, including running awareness campaigns on the harmful effects of irrational drug use, and updating the regulation of drugs and medicines and the registration of health care practitioners. Tighter controls on drug registration, prescription and outlets were suggested.

Training was seen as important and should be developed, with WHO and UNDCP support, for quality control personnel, regulatory and law enforcement officers.

The use and misuse of controlled substances should be included in the training curricula for medical, pharmacy, public health and other health workers. Teachers should also receive advice and training about drug abuse. Public health education programmes should stress the importance of obtaining drugs from licit sources. Assistance should be sought from the UN and other international organisations and youth, women's and religious organisations should all be mobilised.

Continuing education should be provided for all health professionals, who should also be involved in health education campaigns and the training of other professionals in the health, law enforcement and regulatory fields. There should be closer liaison between professionals in all of these fields on the implications of drug legislation.

Finally, professional associations of health care personnel should be encouraged to draw up voluntary ethical criteria on the handling of drugs.

English version of the Chinese Pharmacopoeia

The 1992 Pharmacopoeia of the People's Republic of China is now available in English. Compiled by the Ministry of Public Health, it includes all traditional Chinese medicines and 967 western medicines and preparations, and gives information on the standards of purity and the strength of each drug included. For more information contact: Han Ying Shun Consultants, P.O. Box 71006, Wuhan, Hubei 430071, P.R. China.

HAI Mexico campaigns for better drug use

In its December 1992 issue of Pharmaceutical Alert, HAI Mexico lists drugs on sale in Mexico which have been banned, withdrawn or severely restricted in other countries. The journal is a tool in HAI's campaign to promote rational drug use and the group is keen to receive suggestions on other ways to encourage this. It will also offer a course on rational drug use to interested groups or institutions. Educational materials will be offered to course participants. For more information contact: Dr Delores Vicencio A. Mexico Representative Council A.P. 27960, Mexico 06760 D.F., Mexico.
Cyprus holds second workshop on rational drug use

Further progress towards rational drug use in Cyprus was made in June when a national workshop on this subject brought together 60 pharmacists, nurses, doctors and staff from the Ministry of Health's Pharmacy Department.

The varied programme included sessions on the rational use of antibiotics, antihypertensive and antinauseatic drugs, neuroleptics, tranquillizers and drugs used in oestrogenia. There were also more general sessions on drug use in Cyprus and the future of clinical pharmacy in the country. During this part of the meeting, the workshop's organizer, Dr Louis Panayi, a clinical pharmacist at the Ministry of Health, presented the results of a drug use indicator study in 20 public sector facilities in Cyprus. The study showed an average of three drugs per prescription; 20% of drugs were prescribed as generic; 29% of prescriptions contained an antibiotic; 3.6% contained an injection; 99.6% of drugs were included in the national list of essential drugs.

Among the recommendations drawn up at the meeting were:
- generic prescribing should be promoted in public sector hospitals and clinics;
- every hospital should establish a hospital pharmacists committee to develop prescribing policies and treatment guidelines for common diseases and complaints. Drugs used should be in the national list of essential drugs and be selected on the basis of efficacy, safety, quality and cost. Combination drugs should be avoided;
- every hospital should have a clinical pharmacist who should be involved in the development of local prescribing policies and treatment protocols;
- treatment guidelines should be closely adhered to and a system of audit established to ensure adherence to the guidelines. Specialist departments should have their own treatment protocols;
- professional collaboration between doctors, nurses and pharmacists should be encouraged;
- continuing education and in-service training on rational drug use should be promoted at hospital level;
- all patients should be given a unique health card;
- a drug information and poison centre should be established.

Aberdeen drug management course upgrades to postgraduate status

As from 1994 the course in effective drug management and rational drug use organized by the Robert Gordon University's School of Pharmacy, in collaboration with WHO's Drug Action Programme (see EDM 13), will be granted postgraduate status. The course started in 1992 and has been given twice yearly.

In order to facilitate participation for busy professionals and to keep costs to a minimum, the course has been condensed to nine weeks, which includes a substantial element of "self study". It will be offered once a year in June/July at a cost to participants of £3,600 ($US6,000), which includes tuition, all materials, accommodation and a daily allowance for expenses. The 1994 course will be held from 6 June to 5 August.

Essential Drugs Monitor

LIST OF HOSPITAL DRUGS

The ARAB RESOURCE COLLECTIVE

Resources for Community Health Care and Development

One important way that ARC supports primary health care in the region is by translating relevant publications into Arabic.

To date these include:
- Blitz Pikh, D. Murose,
- Deng Kus, A. Hong, S. van der Geest.
- Problem Drugs (1st ed.), A. Cheeky and D. Gilbert.
- Readers and Activity Sheets from the Child-to-Child Series.

Child health journal launched

The first issue of an international child health newspaper, the Global Child Health News and Review has recently been published. The quarterly journal from the Vancouver based non-profit organization, the Global Child Health Society, is distributed free to child health advocates in 150 countries, with the aim of providing a worldwide forum for discussion and action.

Items featured in the first issue include a report on the Child Health 2000 World Congress which explored key priorities for child health in the next decade, a review of the Earth Summit, held in Rio de Janeiro in 1992, addressed the needs of the world's children, and the public health problems faced by the Commonwealth of Independent States.

For more information contact: Global Health Child News and Review, 5113-590 Beach Avenue, Vancouver B.C. Canada, V6E 4M2.
Harmful human use of donated veterinary drug

In March 1993, 11 Lithuanian women lost their eyesight after using a drug that had been provided through drug donations. The drug was clostrinol, an anthelmintic which should only be used in veterinary medicine, but was mistakenly given for gastrointestinal problems, reports the Lancet, 31 July 1993. The donation had been received without product information or package insert. Doctors tried to identify the product by matching the name on the box with the name on labels of other products. They unfortunately wrongly identified the drug as one for the treatment of encephalitis. After this mistake became apparent the physicians who had prescribed the drug contacted the Whois Drug Information Centre. The Centre was able to identify the product but could not provide information on how to treat the women. The state toxology centre contacted the manufacturer, Janssen, who informed them that there was no antidote. The women have regained their eyesight but still have eye pain and are all unable to return to work.

The Lithuanian health care system is faced with a lack of drugs because of hard currency difficulties and the collapse of the former Soviet systems for the production and distribution of medicines. Imported drugs from Western Europe are available, but are very expensive, and many people are forced to rely on donated drugs. In many cases these drugs are sent and distributed by charity organisations, churches, or individuals. The drugs often arrive out of date and with no product information, or information in the language of the donor country. Partly as a result of foreign pressure, Lithuania accepts all offers of drug donations, which puts an enormous burden on the receiving agencies. They have the task of sorting the donated drugs, finding the relevant product information, and spending scarce resources on translation of package inserts. Lithuania also bears the burden of destroying unusable drugs.

At a press conference on the occasion of the case, Lithuanian Ministry of Health officials stated that nobody can assure that a tragedy like this will not be repeated. The response to international disasters and hardship has commonly been to send donations without assessing the need of the recipients and without careful selection of the products. In response to the difficulties caused by drug donations two sets of guidelines have been developed. The Christian Medical Commission guidelines (see EDM-7), which are available in English, French, Spanish, German and now Lithuanian, explain the principal reasons why drug donations often cause more problems than they solve. They also offer practical guidelines for both donors and recipients to ensure that the donations meet needs. The WHO guidelines are summarised below.

WHO guidelines on drug donations

Whatsoever the source of drugs, it is very important that:

- no drugs should be sent from a donor country without a specific request, or without prior clearance by the receiving country;
- no drugs should be sent that are not on the list of essential drugs of the receiving country, or if such a national list is not available, on the WHO Model List of Essential Drugs;
- no drugs should arrive with a future life (before expiry date) of less than one year;
- labelling of the drugs should be in the appropriate language(s) and should at least contain the generic name, strength, date of manufacture and expiry date;
- labelling on the outside package should contain the same information, plus the total quantity of drugs in the package.

Unnecessary injections increase the risk of AIDS transmission

Data from the Indian Council of Medical Research have shown an increasing incidence of HIV infection in the country. Since the parenteral route of transmission remains the main method of infection in India, health workers are becoming increasingly concerned about the reuse of needles and syringes at primary health centres.

Doctors, aware of the risks, said that patients’ demands obliged them to prescribe unnecessary injections and that complaints were made to local politicians if they refused. For this reason they were reluctant to curb excessive use of injections.

An analysis of 2953 drug prescriptions at two primary health centres in Pondicherry State, South India, showed that nearly half of them contained at least one injection. From a total of 1406 injections prescribed almost 60% were for their placebo effect. Four hundred and seventy four injections were of vitamin B complex but none of the patients had symptoms of vitamin B deficiency.

On average a nurse at a primary health centre gives 150-200 injections a day over a three to three and a half hour period—almost one injection a minute for this 10 glass syringes and 25 needles are provided. This material has to be kept sterilised on a small steriliser, but frequent power cuts mean that a kerosene stove must also be used and it is impossible to ensure adequate sterilisation in these circumstances. Excessive use of injections is widespread, in both the public and private sectors. An intensive medical campaign aimed at prescribers and patients is essential to reduce the number of injections prescribed and in turn to reduce HIV transmission by this route.


India’s first patient education library opens

Patient education is now acknowledged as vital in ensuring good medical care, but unfortunately until recently there has been no patient education library in India, where patients could obtain up-to-date, unbiased and accurate information about health problems and treatment. The Community Health Research Programme in Ashish, Tandar, Bombay 400 034, India has rectified this situation; however, the country’s first such library is now open.

The library is expected to have many benefits for both patients and medical staff including improved patient compliance. It is believed that well-informed patients, who demand the best treatment available, will act as an incentive for doctors to update their skills and for hospitals to improve their facilities.

Staff expect the materials in the library will contribute to preventive medicine by alerting patients to danger signs they would otherwise have ignored and by encouraging a healthy lifestyle. It is hoped that once the public are better informed, the acceptability of patients with diseases involving some form of social stigma will improve. The aim is that the library will act as a stimulus for self-help groups to give mutual support to those with a particular disease. The programme also hopes that it will act as a resource for medical writers keen to ensure the accuracy of their technical reporting.

Health workers as well as patients can benefit from the new patient education library.

RATIONAL USE

How to establish a drug and toxicology information centre in a developing country

Ossy J. Kasilo and Charles F.B. Ntchinda

In most developed countries, centres that provide drug and toxicology information services are not combined because these services are best handled by separate personnel on separate phone lines, with or without the sharing of information resources. However, it is important for developing countries to consider combining the two services due to their limited personnel and resources. One of the advantages is reduction in the cost of operation by the sharing of personnel, information resources, and space. Combining programmes can also provide the drug information service with easier access to, and justification for, improved communication and data-management equipment, and can allow 24-hour service. Moreover, combining programmes will give the toxicology service speedy access to literature search and evaluation skills of the drug information specialists. In addition, by having a reliable source of information and advice from the centre, the community becomes more interested and motivated in preventing poisoning. By recognizing community patterns of poisonings, the centre will be able to issue alerts and evolve responses to avoid further incidents of a similar type. This is the toxicovigilance function of the centre.

Some of the potential disadvantages of having a single staff member provide both services are the differences in personnel skills required, the increase in request volume, and the need to respond rapidly to urgent requests while other evaluations are underway. However, the advantages of combining poison control and drug information services outweigh the disadvantages in developing countries.

The following guidelines are intended to help developing countries that wish to establish or strengthen capabilities for drug and toxicology information centres and related facilities. The guidelines are based on the experience of established drug information centres in developed countries and one drug and toxicological information centre in a developing country, Zimbabwe, which has been operating since 1975. They should be adapted to the local socioeconomic, cultural, and therapeutic norms in each country.

Documentation

The effective functioning of a drug and toxicology information centre depends on adequate documentation. This consists of various components that interact with each other to create a basis for the advice given. There are two categories of data that centres collect. One is data extracted from various external sources (e.g., scientific journals, textbooks, handbooks, reports, and data sheets, as well as data from other centres). The other category includes data extracted internally from observations made within the information service staff and from follow-up of poisoning cases, including those hospitalised. It is essential for centres to have data on local chemical products as well as on natural toxins, poisonous plants, and animals. A drug and toxicology information centre should have its own library. In addition, books and other publications should be accessible to the centre from other relevant sources of information, such as a medical and/or pharmacy school library.

The hierarchy of the literature sources is conventionally divided into the three groups indicated below. When the centre is well established, it might be difficult to have a full range of all the sources. However, for adequate functioning of a drug and toxicology information centre, provision should be made to have samples from all three categories of drug information sources.

General (tertiary) information sources (see Table 1): these sources present, in a condensed and compact format, documented information from a background of publication in the primary literature. Examples include textbooks, general reference books, review articles, compilations, and drug compendia. It is advisable to use the most current sources available.

Secondary information sources (see Table 2): these functions as a guide or direct line to the primary literature. They are usually indexing (Index Medicus) or abstracting services (International Pharmaceutical Abstracts) and microform (Iowa Drug Information Service). The latter needs microfiche reader-printer equipment and therefore usually is much more expensive. There are two types of retrieval systems: manual and automated.

Primary information sources (see Table 3): these are the foundation on which the previously discussed literature classification relies. They include journal publications dealing with scientific and nonscientific data with particular emphasis on drug-related subjects such as reports of clinical drug trials, case reports, and pharmacologic research. They contain current citations.

Table 1: Examples of general (tertiary) information sources

<table>
<thead>
<tr>
<th>Drug Information Sources</th>
<th>Description</th>
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<tbody>
<tr>
<td>Encyclopedia of drugs and poisons</td>
<td>A comprehensive guide to drugs and poisons, updated annually.</td>
</tr>
<tr>
<td>Index medicus</td>
<td>A Swiss pharmacists' society (updated every two years).</td>
</tr>
<tr>
<td>Merck index</td>
<td>A reference tool for drug identification, updated regularly.</td>
</tr>
<tr>
<td>USP compendia</td>
<td>United States Pharmacopoeia (updated annually).</td>
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<tr>
<td>AAS drug evaluation</td>
<td>American Association for the Study of Drug Addiction.</td>
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Pharmacology and therapeutics


Clinical toxicology


Table 2: Examples of secondary information sources

<table>
<thead>
<tr>
<th>Source Name</th>
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<tbody>
<tr>
<td>Annual review systems</td>
</tr>
<tr>
<td>Clinical pharmacological therapeutic findings, Cincinnati, Harry Whitty Books. A monthly publication that contains detailed information on drug therapy from the world literature. It includes reasonably inexpensive drug interactions, scoring factors affecting drug action, adverse reactions, and drug and side compartment. A translated abstract index is supplied.</td>
</tr>
<tr>
<td>Current contents of clinical practice, Philadelphia: Lippincott for International Information. A compilation of the contents of up to 300 periodicals in medicine. It is a weekly publication issued twice a year, offering a preview of the latest information in drug therapy and its ramifications from pharmaceutical and medical literature.</td>
</tr>
<tr>
<td>Index medicus, Bethesda, MD: National Library of Medicine, US Department of Education and Welfare. An indexing service to the world scientific literature. About 50% of the articles indexed are drug oriented. Abstracts are available in translated versions from international publisher.</td>
</tr>
<tr>
<td>International pharmaceutical abstracts, Washington, DC: American Society of Hospital Pharmacists. A monthly publication that provides articles from more than 200 journals covering pharmacy, the pharmaceutical sciences, and the clinical and sanitary aspects of drug therapy. It requires regular access to a good scientific library, or mobile device will not be possible.</td>
</tr>
<tr>
<td>Clinical data, Chicago, NJ: Pharmaceutical Documentation, a monthly publication that provides information on medicinal drugs and related topics.</td>
</tr>
<tr>
<td>Pharmacy, New York: ACP Press. The most recent (weekly) secondary source available and probably the most useful along with Current Contents for obtaining the most recent information. It presents abstracts weekly from international journals, as well as bibliographies on major topics of current research interest. A quantity index and major index ordering are also supplied.</td>
</tr>
<tr>
<td>Focal points, London: ADM Press. A weekly publication of abstracts on active drug interactions from international journals, with indexed tables and an alphabetic standardized abstract index tables to provide lists of drugs as part of the subscriptions.</td>
</tr>
</tbody>
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<tr>
<td>Annals of Internal Medicine</td>
</tr>
<tr>
<td>Archives of Dermatology</td>
</tr>
<tr>
<td>Central African Journal of Medicine</td>
</tr>
<tr>
<td>Drug Information Bulletin</td>
</tr>
<tr>
<td>Journal of Clinical and Investigative Pharmacy</td>
</tr>
<tr>
<td>British Journal of Clinical Pharmacology</td>
</tr>
<tr>
<td>Clinical Pharmacology and Therapeutics</td>
</tr>
<tr>
<td>Drug Information Journal</td>
</tr>
<tr>
<td>European Journal of Clinical Pharmacology</td>
</tr>
<tr>
<td>Journal of Pharmaceutical and Biomedical Analysis</td>
</tr>
<tr>
<td>Veterinary and Human Toxicology</td>
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<td>WHO Drug Information</td>
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Table 3: Examples of primary information sources

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**Essential Drugs Monitor**

and the community in providing such information. In addition, two full-time pharmacists who can also be involved in teaching, a research staff where applicable, a staff development fellow or research assistant, and advisors in specific areas are also desirable.

When establishing the centre, the aid and advice of a variety of medical and non-medical specialists should be drawn upon. The development of the centre expands it may be possible to include some of these areas of expertise on a part-time basis as advisors. These specialists should be able to collaborate in the activities of the centre and to provide, whenever necessary, specific information on the subjects of their expertise.

**Office**

The number and size of the rooms will depend on the facilities and the number of personnel available. However, the rooms should be large enough to allow for efficient functioning, storage and retrieval of documentation, and the handling of equipment. The centre's location depends on its objectives and potential users. It should be established either within the university or a public institution or hospital or a combination of these. The location might decide to establish the centre within the framework of a drug regulatory authority, which can be the pharmacy, the drug control council, the centre under the ministry of health. This is to minimise bureaucratic and administrative delays, and to ensure an independent and immediate decision-making process, which is often required in this field.

Adequate staffing (considering the inadequacy of conditions in many countries) is required. We believe that the centre should be involved in drug and toxicology information research, training, and education. Therefore the vehicle will be used by personnel for the collection of data from provincial, district, and rural areas and for educational trips.

**Equipment and facilities**

In order to function adequately, a drug and toxicology information centre requires certain basic equipment (e.g., word-processor, printers). Other necessary equipment includes stationary and duplicating equipment, photocopier, computer, microfiche, reader-printer for the Iowa Drug Information Service, and typewriter.

Two telephones are a minimum and possibly other means of communication (e.g., telex, telex, short-wave radios) might be desirable. Moreover, an answering machine is necessary if the service is operated outside office hours within a hospital and university/academic institution has the advantage of providing a network of media for a continuous service and enrich the work, allowing more complete knowledge of the clinical aspects of poisoning and easy access to libraries, research facilities, and academic/educational activities.

**Legal status and financial support**

Sources of finance depend on the objectives of the centre. However, it is imperative that drug and toxicology information services, like quality control laboratories, remain neutral, independent, and autonomous, and set out to carry out their functions. As a drug and toxicology information service is considered a public health service, it should be officially recognised by governmental authorities. Government resources are the most suitable source of financial support, provided these authorities respect the above-mentioned conditions. The services they provide should be free to the enquirer, particularly in an emergency, but charges may be made in certain non-emergency cases. Financial resources can also come from different sources, such as the university, hospital, associations of medical and commerce, philanthropic groups, and other organisations.

If the centre is independent, the main part of its budget will be devoted to salaries. It should be borne in mind that the maintenance of current resources is essential. Another important portion of the budget should be devoted to the maintenance of equipment, e.g., the telephone, telefax, telex, and computer systems. Capital equipment costs should be allowed for in the financial structure of the budget. Estate management costs should be allowed for by the administration of the building used by the centre.

**Exposure/visibility**

The centre should be accessible to healthcare providers and to the public in order to be fully used. It should be publicised through its establishment by brochures, television, posters, and seminars. Communications facilities (e.g., telephone) should be included in the directory or telephone book and pointed out to the telephone operator.

**Twinning arrangements**

Twinning arrangements between centres in both developing and developed countries are very valuable, enabling exchange of information and staff for teaching and training. Rapid international communication links by telephone or telex are essential. Telefax can be particularly valuable in transmitting required information in an emergency.

**Human resource development**

The evolution of the drug and toxicology information service should have a career structure similar to those of academia and educational services. All staff members should have the opportunity for additional training and advancement within their own capital facilities. Where appropriate, professional staff should be encouraged to undertake relevant research activities.

**Summary**

We recommend that national drug policies in developing countries should include provisions for the establishment of combined drug information and poison control centres. Such centres should be part of the teaching and training and continuing education for health professionals and the public and should therefore be located in a major medical school. A WHO and similar organisations should play a role in establishing such centres.
RATIONAL USE

Sri Lankan students campaign for rational medicine: the story of SIRHA

Sanjiva Ranwella*

This second article in our series on organizations concerned with rational drug use features a very different group from the long established Commonwealth Pharmaceutical Association described in EDM-13. Today we look at the work of SIRHA (Students Involved in Rational Health Activities), a young and relatively unknown organization founded by medical students. SIRHA members believe that even in this formative stage of their lives, they have a voice that needs to be heard, coupled with a commitment to promote change towards more rational use of resources and people centered health care.

Students in general, and medical students in particular, often have a natural curiosity and are keenly interested in getting their studies and passing demanding professional examinations. But rather than questioning or trying to change the status quo, this attitude is perhaps understandable and yet modern medicine cannot be studied in a scientific vacuum, but has to be part of the much broader public health perspective. Inextricably linked to disease prevention, treatment and cure, are issues of resource priority, accessibility of services and medicines, community empowerment, the availability of objective information, and the control of drug quality, use and marketing.

Until recently there has been little student involvement in promoting health activities and people oriented health care in Sri Lanka. Why? Perhaps a vital link was missing.

This missing link was provided by the IUCU Asia-Pacific Workshop on Pharmaceutical Health Ministry Officials held in Colombo in June 1992. A number of Sri Lankan medical students were observers at the meeting and also used the informal discussions that took place out of seminar hours to increase their knowledge of issues related to rational health care. Stimulated by the concerns and issues raised, and pharmaceutical policies evolving in different countries of the region, the students decided that they wanted an active role that would enable them to take awareness and participate in action on health care issues in their own country of Sri Lanka. One month later the new group, entitled Students Involved in Rational Health Activities (SIRHA), was officially established.

From its inception, SIRHA has tried to critique constructively the existing health care system. SIRHA is not ready to accept things as they are, but wishes to participate in identifying and working towards what they should be. It argues that if the situation cannot be changed immediately, it can at least be questioned and improved.

Increasing the awareness of the concept of rational health care among medical students started with information collection on the subject. Generous contributions to this end were made by the Health Action International (HAI) office in Amsterdam and the WHO Action Programme in Geneva. These publications have formed the nucleus of our mini-library, which is extensively consulted. Our advisory board consists of members of the academic staff of the Faculty of Medicine, University of Colombo, who are also the leading advocates of health care reform in the country.

The organization has been very active in its short existence. One of the first events was a seminar on "rational therapeutics," organized by SIRHA for the medical students. SIRHA presented case histories of inappropriate drug treatment and invited clinicians and academicians to discuss them.

Members participated in a panel discussion organized by the International Advertisers Association to discuss the level of control that should be applied to medicinal drug advertising. We expressed our views vigorously, radiating many critical issues. This was probably the first time that the voice of students had been heard during a meeting on drug promotion.

One of the major events in our first year was a seminar on "How to facilitate the provision of low cost quality drugs based on rational prescriptions to all Sri Lankan consumers," organized in collaboration with the Ceylon Medical Journal and the Organization to Safeguard Life and Environment (OSLE). This group consisted of government officials, including the Director-General of Health Services and the Chairman of the State Pharmaceuticals Corporation. Participants included academics, clinicians, policy makers, the media, pharmacists and medical students. Drug registration, tenders, local manufacture, quality assurance, distribution and pricing were discussed at the seminar by the resource group. During the lengthy sessions specific targets to achieve the workshop's objectives were identified for various groups, and an action plan is now being drafted.

In February a "pharmaceutical guerrilla attack" was carried out by SIRHA members at the annual meeting of the Sri Lankan Medical Association, attended by academicians, clinicians and other health care professionals. Many pharmaceutical companies have promotional stalls at this venue. On the first day SIRHA members collected examples of promotional material on display. Some inappropriate statements on several products were chosen for "attack" and a leaflet was prepared containing these statements and comparing them with the text of internationally recognized standard works of reference. The leaflets were then distributed to meeting participants.

One of the advertisements was the subject of the Medical Lobby for Appropriately Advertising (MALAM) initiative letter for August 1993. We have also taken steps to prevent inappropriate and misleading advertising of health related products in the mass media, and have already been instrumental in bringing about the withdrawal of an advertisement containing misleading and unsubstantiated claims by one leading multinational company operating in Sri Lanka. We consider that action is badly needed in this area which has been neglected for many decades. Unfortunately, there are numerous examples of misleading marketing.

One recent SIRHA activity was the widely publicised complaint we submitted to the People's Tribunal (Mahajana Vikalpa Vishishtachaya Mandalsaya - MVVM) on the current situation of pharmaceutical pricing, unethical promotion and the availability of an irrationally large number of me-too drugs in this country. The MVVM is an independent forum consisting of professionals, academics and other eminent persons in public life. Although it has no legal status it examines matters of public interest and places its verdict before the public, backed by its considerable moral authority. The Tribunal concluded that the complaint was well founded and strongly recommended that the regulations prescribed by SIRHA to rectify this alarming situation be implemented without delay.

In July this year, SIRHA also held seminars on the pharmaceutical industry for the students at the Faculties of Medicine at Galle and Ragama, which were attended by a large number of students as well as members of the academic staff.

Currently some of our members are reviewing pharmaceutical advertising practices in Sri Lanka. They have already found some advertisements which are not acceptable under any circumstances and these findings will soon be published.

We do not live in an ideal world and it is increasingly apparent that this type of campaigning approach to health care is not welcomed in many quarters. On the other hand, SIRHA has been able to establish sound relationships with many interested organizations, both local and overseas. These include the WHO Drug Action Programme, Health Action International (HAI), Action for Rational Drugs in Asia (ARD), the International Organization of Consumer Unions (IOCU), the Organization to Safeguard Life and Environment (OSLE) and the Medical Lobby for Appropriately Advertising in Sri Lanka (MALAM). MALAM has now appointed SIRHA as its associate in Sri Lanka.

Where do we go from here? We intend to continue our focus on promoting people oriented health care. We plan to publish a news bulletin on health issues, featuring academic and clinical writers and some students. Our membership consists of students with experience in journalism, which will make this undertaking easier.

We believe that we have broken new ground in Sri Lanka. It has not always been easy but we have been helped by feeling part of a global network of individuals and organizations with a common goal of more equitable and rational health care. We hope not only to survive but to strengthen our membership and activities and to expand into other faculties. We want to show that students can and should have a voice in promoting drug prices and fees for charge, rational health services and the wise use of limited resources concern us all. Q

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A pre-school clinic in Colombo. SIRHA hopes its activities will contribute to better health care for all in Sri Lanka.
RATIONAL USE

Barbiturate combinations: risks without benefits

Robert Hartog

Barbiturates are a group of substances derived from barbituric acid, which affect the mind, and have been used for almost a century as antiepileptics, hypnotics, tranquilizers, or anaesthetic agents. Barbiturates belong to the most thoroughly investigated group of substances used in medicine. Consequently, much has been published on both the desired and undesired effects of these drugs. They have a wide range of inhibitory effects on the central nervous system, from mild sedation to coma, depending on the substance used, the dose and dosage form. The degree of effect also depends on the individual patient, and the extent to which tolerance develops following use in the past. Barbiturates were and are used primarily as tranquilizers (sedatives), as sleeping agents (hypnotics), as anaesthetic agents, and as anti-convulsant agents (anti-epileptics). Barbiturates are still of indisputable value in the treatment of epilepsy and for inducing anaesthesia, but they should no longer be used as hypnotics or tranquilizers, for which they have been replaced by benzodiazepines which are less dangerous.

Many risks and dangerous side-effects have been reported for barbiturates. These include:
- Drug dependence, associated with withdrawal syndromes following sudden discontinuation of the drug.
- Development of tolerance (i.e. higher doses are required to produce the same effect).
- Induction of other liver enzymes, thus affecting the metabolism of other substances.
- A comparatively narrow safety margin. Other possible but less common side effects include: vasodilation and thrombosis following intracranial injection; allergic reactions; skin rashes and eruptions and bronchial spasms; impaired liver function or even liver necrosis; immunological diseases; lupus erythematosus; pemphigus vulgaris; Stevens-Johnson syndrome; and acute porphyria.

Although barbiturates have been in use for a long time, new adverse effects continue to be discovered, for example, a description of connective tissue diseases following long-term intake of barbiturates was published in 1989.

Despite their dangers, our recent study (see publication details below), which included the regulatory status of barbiturates in 41 countries (18 in Europe) found that they are still sold as hypnotics or tranquilizers in many countries, and even (e.g. Italy) as the over the counter (OTC) drugs. Furthermore, a very wide range of barbiturate combinations (containing more than one active ingredient) products are available in different countries, from one product in the United Kingdom to 319 in the United States of America. As a manufacturer is unlikely to supply a product unless it can be expected to bring in a certain level of sales, it can be more or less concluded that the availability of a good number of products indicates considerable sales.

Barbiturates are sold in combination with a number of different substances, including both herbal remedies. These combination products are mainly old products, obsolete drugs which are still on the market. Although clinical pharmacologists have warned against the use of these drugs for at least 15 years there has been little critical public reaction to this issue. This is probably why these products are still widely available today.

Regulatory authorities appear to have the impression that this is a problem that will resolve over time and requires no further attention. But are we not already in waiting another 15 years in the view of the risks involved?

The solution is not simply to replace the barbiturate combinations with other substances, for example, benzodiazepines. Many of the arguments put forward - that these combination products are obsolete and potentially hazardous - apply equally to combination products containing other psychotropic drugs.

Our research concluded that barbiturate combination products have a high risk potential, and have not been shown to be of therapeutic value in any studies that satisfy the EC conditions for the listing of combination products or any other scientifically designed clinical studies in the interests of pharmacological and public health. National regulatory authorities should act now to ban such products - with the exception of anti-epileptic combinations and - industry should cease their manufacture and promotion.

References

Dr Robert Hartog is a physician, public health specialist and researcher, who has acted as consultant for the World Health Organization in a number of countries. He is currently working on a primary health care project in Santiago, Chile. A publication based on his research entitled Barbiturate Combinations: Risks without Benefits was published jointly by the BUKO Pharma-Kamouflage and Health Action International. It is available in English from HAJ, Jacob van Lemperskade, 354 T NL-1053 SJ Amsterdam, The Netherlands, and in German from: BUKO PK, August-Bebel Str. 62, D-33002 Bielefeld, Germany.

Regulatory status of barbiturate combinations in various countries in 1991

EUROPE

Austria

Combinations with hypnotics have been banned since 1.6.1990.

Combinations with analgesics or anti-inflammatory agents since 1.1.1992.

A complete ban on barbiturate combinations is planned.

Belgium

Combinations with analgesics, other hypnotics or sedatives, gastrointestinal products and products for heart disease and disorders of the respiratory tract have been banned. Some other products contain barbiturates in doses of less than 400mg per single dose and less than 800mg per daily dose are still available without prescription but a ban is being planned.

Finland

Following informal discussions with the manufacturers, these products were withdrawn from the market.

Hungary

Barbiturate combinations were excluded from the standard recommendations for treatment (Formulae Normales) in 1977; four barbiturate combinations were withdrawn in 1988. National consumption of phenobarbital then decreased by 80%. Annual consumption amounted to 1.00 million DDD in 1997, corresponding to about 1 DDD/day for every 25th member of the population. A popular product that contained phenobarbital and naltidoxylamine was available without prescription accounted for over half of consumption.

Ireland

There have been no new registrations since 1974. The manufacturers were requested to withdraw these products in 1977; again, resistance to a ban.

Italy

Combinations of analgesics and low-dose barbiturates are still available without prescription.

Sweden

Letters were sent to the manufacturers in 1984 informing them that the government was planning to review registration of these products. Manufacturers responded by withdrawing these products "voluntarily."

Switzerland

Prescription-only status for these products was introduced in 1984.

United Kingdom

The measures adopted by the Medicines Control Agency amount to a ban on barbiturate combinations. Only one product is still on the market whose use is restricted to patients already dependent on barbiturates and for whose insomina no other treatment is available.

NON-EUROPEAN COUNTRIES

Australia

The Australian Drug Evaluation Committee recommended the withdrawal of all barbiturate combination products. Following demands by the regulatory agency, manufacturers withdrew these products between 1986 and 1990.

Chile

Following demands by the government (1988) to produce justification for these combination products, several manufacturers withdrew their product.

Costa Rica

The special controlled prescriptions for hypnotic drugs are not required for combination products in the barbiturate content is considered low.

India

Manufacture and marketing of sedatives or hypnotics with analgesics or antipysychotic agents were banned in 1991.

Philippines

In accordance with the new guidelines on combination products dated 19.9.1990, barbiturate combinations had to be withdrawn from the market or re-formulated by March 1992. As the guidelines include a clause on exceptions, it is not certain that marketing authorisation for all barbiturate combinations has actually been withdrawn.
RATIONAL USE

Rational drug use workshop for universities in Pakistan

From 20-22 August 1993 a very successful workshop was held at Bhurban, in the Murree hills north of Islamabad. Over 60 professors of pharmacy, pharmacology, and internal medicine from 18 medical and six pharmacy schools in Pakistan and Afghanistan attended. To promote the essential drugs concept and rational prescribing could be included in the undergraduate curricula. Officials from the Ministry of Health, professional associations and nongovernmental organizations also attended the workshop.

Apart from the lack of essential drugs in rural areas, irrational prescribing is probably the most serious drug problem in Pakistan. Results of prescribing studies presented at the workshop indicated that almost 40% of prescriptions contained one or more antibiotics, a figure which is much too high to be justified. In addition, polypharmacy is very common, with an estimated 3.6 drugs per prescription, and an average of 16.5% of prescriptions contain at least one. It was surprising to note that this pattern was consistent for all levels of the health care system: general doctors did not prescribe 5% better than paramedical staff, and specialists did not prescribe better than general doctors. In a large study on the treatment of diarrhoea, all three levels prescribed antidiarrhoeal drugs in about 30% of cases, metronidazole in 22%, and antibiotics in 40%, only 6% were treated with ORS alone! This again constitutes clear proof that it is essential for clinical specialists and university teachers to give a good example of rational prescribing, because their prescribing pattern will be imitated all along the line.

It may be difficult to change existing prescribing patterns, particularly among the many private doctors. It is therefore of great importance that rational drug use is not only taught in Pakistan's medical schools but actually practised by the clinical teachers, to ensure that at least the future generations of doctors have a different attitude.

The very positive and creative atmosphere at the workshop is reflected in some verses of the (much longer) farewell poem presented by one of the participants.

The ESARO was the sixth in a series of eight workshops for medical and pharmacy schools in the WHO Eastern Mediterranean Region. A single report will be prepared to cover all workshops, which will include the main presentations by the various national and international experts.

South-East Asian countries discuss strategies for better drug use

Although most South-East Asian countries have national drug policies and essential drugs lists, inappropriate drug use, with its adverse health consequences, remains a serious problem. This was the principal message of Dr Ko Ko, WHO's Regional Director for South-East Asia (SEARO), speaking in New Delhi at a WHO conference on drug strategy in the region. Activities to promote the better use of drugs should be based on a knowledge of local prescribing patterns and drug use, said Dr Ko Ko, and they required a co-ordinated effort involving many agencies and groups, such as ministries of health, universities, professional organizations, regulatory agencies and NGOs.

The SEARO meeting, which was organized in collaboration with and support from the Action Programme on Essential Drugs (DAP), was a follow-up to a consultation in 1991 that had identified rational drug use as a priority area. Senior officials and academics from Bangladesh, Bhutan, India, Indonesia, Maldives, Mongolia, Myanmar, Nepal, Sri Lanka and Thailand, and resource personnel from DAP and the Regional Office, shared experience with the aim of developing national and regional strategies to improve the use of drugs by health professionals and the general public.

After country presentations illustrating a wide diversity of national activities and policy development, participants split into two groups - one to focus on national and the other on regional strategies. The "national" group emphasised that drug policies must include a commitment to promote rational drug use. Essential drugs lists, standard treatment regimes, availability of objective drug information, and hospital therapeutic committees were cited as some important strategies. It was recommended that countries should develop their own criteria for regulating drug promotion, based on the WHO Ethical Criteria for Drug Promotion and Marketing. The group also examined the issue of drug donations and proposed that countries discourage donations of products not included in their national essential drugs list, since these could hinder rather than help appropriate drug management and use.

The importance of rational drug use as an essential component of national drug policy and intercountry collaboration was also stressed by the "regional" group. Different national socioeconomic, cultural and technical considerations made it difficult to draw up a detailed plan, but the group recommended that the highest priority be given to inter-country exchange of information on activities to promote the appropriate use of drugs.

The conference provided a good opportunity to review the current situation of rational drug use in the countries and for participants to discuss and learn from the experiences of others, and avoid "reinventing the wheel". No bold or radical shifts in direction were proposed but the general aim was to develop and consolidate what had been already achieved.

Patient leaflets

The EC Commission could draw up new rules on patient information leaflets following the findings of a pan-European consumer survey conducted by the Belgian consumer organization CRIOEC at the Commission's request. Consumers want more attractive, easy-to-read inserts than the scientific leaflets they get now. The EC's 1992 medicine leaflet and labelling directive, which came into force at the beginning of the year, says that information for the patient must be complete and comprehensible, but it does not specify print size or wording.

The survey found that most consumers do not understand terms such as "indications" and "contraindications". It called for leaflets to have seven main headings in question format. These were:

- What is (insert product name)?
- Why use ....?
- When should ..... be/ not be used?
- What precautions should be taken?
- - children
- - pregnancy
- - breast feeding
- driving or operating machinery
- other medicines
- How should I take ....? - adults
- children, what should I do if I miss a dose, take too many tablets?
- What undesirable effect may ..... cause?
- How should I store ....?

The report also recommends that the print size adopted be the same as that in most European newspapers.

Andean States develop common pharmaceutical policy

In the Andean countries a consensus has been reached on two major pharmaceutical policy lines: the first, which is fundamental, is to promote ESSENTIAL DRUGS as the best approach from the public health viewpoint. This is underlined by promotion of GENERIC DRUG use as the best commercial alternative.

Similarities in the health systems, patterns of disease and processes of social and economic change, combined with a desire for market integration, have all made the development of a joint drug policy for the Andean area a priority. After several meetings on the harmonisation of technical aspects of the pharmaceutical sector, representatives of the five Andean countries: Bolivia, Colombia, Ecuador, Peru and Venezuela, with the support of WHO's Action Programme on Essential Drugs and its Regional Office for the Americas, have adopted a common pharmaceutical policy to be implemented in the sub-region. The new policy covers such areas as legislation; selection (with a common essential drugs list); quality assurance; supply; and logistics; financing; rational use; industrial development; and an Andean common drug directory.

The aim is for a comprehensive, consistent and long-term pharmaceutical policy, which also recognises the limited role that drugs play in health care and seeks to highlight the fundamental importance of living conditions, healthy lifestyles, community participation, promotion and prevention in determining public health.

The official text of the policy, agreed by government and health officials at Cartagena, Colombia, in March 1993, is in Spanish, a translation for the Monitor is given below.

Introduction

Since Alma-Ata (based on the experience of pioneering countries, such as Peru) the primary health care strategy has involved the adequate supply of essential drugs as a basic component of the delivery of health services. Further developments (e.g. Conference on the Pharmaceutical Sector, Nairobi, 1985) ratified the relevance of essential drugs within the policies for extending coverage and rationalising the use of resources.

In the Andean region, some important steps have been taken since the Cartagena Agreement (1973-1975) regarding both cooperation mechanisms between countries and the establishment of technical criteria to generate a common Andean drug market. This will require the resolve of support of the highest political decision-makers.

The similarities in the patterns of disease and mortality in the countries of the sub-region, in the health systems and in the current processes of social and economic transformation, combined with the desire for integration of markets, have made a development of a joint drugs policy for the Andean area a priority. These efforts must be integrated with social and health policies and be consistent with the economic changes, without losing sight of the fact that drugs have health and social functions that must be ignored and that it is up to the health authorities of each country to regain their natural leadership in decisions affecting the manufacture, marketing and utilisation of drugs.

In tackling the task of defining a pharmaceutical policy for the Andean region, it has to be borne in mind that this policy must be consistent, comprehensive and long-term. Very often, for specific reasons, there is a tendency to give priority to partial aspects, such as registration, quality and purchasing, but a fragmented approach subsequently reduces the policy efficacy.

Policy objectives

The role of the state in the pharmaceutical sector, whatever the political ideology may be, is to ensure availability and equal access by the entire population to effective, good quality drugs at affordable prices and to ensure their proper use. The accessibility and availability of drugs are parameters for measuring the quality of the health services and constitute social indicators of justice and equity within the distribution of a country's wealth.

State responsibility for ensuring availability and access is a function that cannot be delegated, although it can be implemented by very different mechanisms and with various forms of participation by the private sector. Far-reaching processes of change, under way in all the countries, involving redefinitions of functions, modernisation, greater administrative flexibility, economic liberalisation and changes in health systems. It is the task of the health sector to make such changes compatible with policy proposals. Producers must restore the normative role of the public sector, such as drug registration, but must also identify mechanisms for linkage with the health services, where drug management is located.

Andean countries have been reaching on promoting two major policy lines: the first is fundamental and concerns the promotion of ESSENTIAL DRUGS as the best approach from the public health viewpoint, and this is supplemented by the promotion of programmes of GENERIC DRUG use as the most commercial alternative.

The selection of essential drugs, those that are the most useful for dealing with the majority of health problems, cuts down the number of products to be manufactured, promoted and marketed, thereby making it easier for health professionals and patients to become familiar with them. Their mandatory use in the public sector and their value for the private sector, facilitate the processes of selection, purchasing, storage and distribution, especially in rural areas.

Generic drugs, by permitting identification of the product by its scientific name and make it easier for the prescriber to dispense and user to choose between many alternatives competing in terms of quality, price or convenience. They introduce competition and transparency by market forces to the supply of drugs and by making advertising and prices transparent, they improve the quality of brands and by promoting the availability of information, they protect the manufacturer. In this way, manufacturers can claim a large share of the market and products can be produced and marketed by any firm, whether they are patented or not.

The criteria for determining which drugs are the most suitable from a public health viewpoint must take into account the availability of reference standard protocols for the most common diseases. This not only makes the systems for calculating quantities simpler and more technically accurate but also permits treatment and products follow-up and evaluation.

The Andean Group has made substantial progress in the harmonisation of national essential drugs lists. Their adoption by each of the countries is an additional factor that will facilitate the integration of the processes. Accordingly, the countries of the Andean subregion undertake to draw up a common list of essential drugs and the relevant macromolecular standards and registration requirements, to set up the Andean Review Bureau and to apply a subregional therapeutical formulary.

Quality assurance

A system of drug quality assurance is a prerequisite for the safe and effective use of drugs. It must have a responsive attitude by the manufacturers and the capacity for verification and sanctions by the health authorities. In an economic scenario, quality is an increasingly critical aspect.
Quality assurance cannot be confined to laboratory analysis but must extend to the entire process of drug supply and utilization. All countries are agreed on the joint implementation of Good Manufacturing Practices (GMP) as the most effective mechanism, together with the development of inspection capability. This is the most important requirement for the implementation of the Andean Quality Certificate approved by the five countries to support the proposals for integration. Nevertheless, the strengthening of the central reference laboratories, the construction of decentralized networks, and the accreditation and validation of independent laboratories for analysis continue to be of vital importance. Selective sampling programmes applying criteria of health hazard (products with a narrow therapeutic spectrum, sterile products, products with potential bio-equivalence problems) and of high consumption will help to focus activities on these manufacturers (production areas) that present major problems. Public dissemination of the findings will be a powerful tool for cleaning up the market.

Sanctions with respect to adulterated or defective products are currently weak. Unless health authorities develop the capacity to take action when faced by situations that threaten individual and community health, quality assurance loses its most important and effective weapon.

The institutional framework for quality assurance is under discussion, both the sources of funding for the laboratories and the problem of retaining qualified staff. Greater administrative and financial autonomy, a high technical standard, and administrative mechanisms to make the laboratories self-supporting by charging for services would seem to be needed.

Supply, marketing and logistics

Guaranteed access, especially for the poorest members of the population, is another commitment for the state. It can involve agreement with the manufacturing sector on rationalizing the production of the most effective and suitable products for the most common diseases in each country. Industry can not only be an ally of the public sector but also contribute concretely to its social service dimension.

However, while there are distortions in supply, there is also much that needs to be done regarding demand, especially in public sector purchasing systems. Introduction of mandatory use of the essential drugs lists, the development of systems for calculating needs and standard treatment protocols for the most common diseases, are areas where tangible results are urgently needed. These measures must be combined with the training of purchasers (such as information on suppliers) and those responsible for storage and distribution.

Experiments with subregional exchange of information on suppliers and prices need to be revitalized and strengthened.

Among the current trends to decentralize the administration and delivery of health services, the most suitable approach would appear to be a balanced combination - in accordance with the specific features of each country - of the advantages of decentralisation (adjustment to needs, timeliness, supervision by the people concerned) with the addition of negotiating capacity (pooled purchasing).

Modernisation and technical improvement of purchasing procedures are being undertaken by various institutions, which are gradually adopting essential drugs lists, treatment protocols and training in purchasing, since such measures can enhance consumer satisfaction and quality of care.

It is also necessary to press ahead with training programmes in good storage practices, an area where there are often great shortcomings.

Important participatory experiments, in the form of cooperatives serving the community, are taking place throughout virtually all of the Andean subregion. With community participation and oversight, essential drugs are offered at affordable prices and viable mini-companies are being set up. The strengthening of such systems, especially through technical assistance, supervision and training, can increase the availability and accessibility of essential drugs.

Financial aspects

The trend in drug prices is towards dismantling administrative control mechanisms. This is not just because of new ideas about the role of the state but also because those mechanisms have not always been free from serious problems. Prices that are inconsistent with the cost structures for political reasons, distortions in the market, corruption, etc., have always been disturbing weaknesses of such systems to a greater or lesser extent.

Under the new policies, the most effective controls should be sought within the market itself; a dynamic and well-supplied market with adequate information, rules governing competition and genuine opportunities for choice, would seem to offer the best guarantees that drug prices match cost structures. In any case, the state should reserve its right to watch over the market and to intervene when necessary to correct any distortions and abuses that may arise. Each country will identify the mechanisms and stages it considers most appropriate to market regulation.

The general principle of cost recovery in drugs programmes is healthy provided that the universal right to access is respected and monitored, with special attention paid to vulnerable groups. Free drugs for all may lead to various forms of black markets, resale, over-prescribing and waste. In the light of very clear criteria which give priority to attaining an affordable price for drugs, proposals for "flexible recovery" of the cost of drugs may be explored; such as direct sales, volume discount and proposals for "cost sharing" even in prepayment programmes, to avoid excessive cost.

This can still be compatible with mechanisms for partial or total subsidy in accordance with criteria focusing on specific social groups (groups with least resources) or health programmes (the special programmes on communicable diseases run by the health ministries).

Drug donations deserve special mention. All too frequently, they become an opportunity for donors to get rid of products that are irrelevant to local needs, out-of-date and often impossible to use because they are unknown or labelled in a foreign language. Their waste is compounded by the enormous resources that have to be invested in storage, transport and sorting. Health authorities should draw up lists of drugs that are acceptable as donations.

Pharmaceutical patents have been adopted by the Andean Group. As this policy of intellectual property is in place, the following criteria could contribute to better future policy definition and implementation.

(a) There should be a mechanism for recognizing the intellectual property rights of each invention, guaranteeing a fair economic reward for the research undertaken.

(b) This mechanism should guarantee not only the rights of the inventor but also the rights of society to derive the greatest possible benefits from the invention. Mechanisms inspired by the present compulsory licences will enable many manufacturers to market their product, awarding royalties to the innovator throughout the duration of the patent.

(c) In the light of the current liberalisation and internationalisation of markets, there is a need to guarantee the right of every product that is legally marketed (i.e., by payment of the respective royalties to the owner of the patent) to move in international commerce; this is the only way to avoid the formation of monopolies at the national level.

(d) The state should reserve the right to intervene on patent matters in cases of health emergency or for serious public health reasons.

Rational use

There is plentiful evidence of the inappropriate use of drugs, not only through self-medication or unauthorised prescribing by the retailer, but also inadequate medical prescribing. It should not be forgotten that all drugs involve some risk which must be balanced by their potential health benefit. Risks include those resulting from shortcomings in professional or technical education and consumers' misconceptions and exaggerated expectations about the role of drugs, that lead them to demand useless, excessive or even dangerous medication.

Potential educational activities in this field cover a wide range and should encompass all involved. Those directed at users (patients) should aim to change inappropriate ideas and attitudes and also to safeguard the users' right to full information. Self-medication merits special attention, for it is important not just to draw the public's attention to the risks involved but also to explain under what circumstances commonly used products are safe and effective.

Prescribers' education is of greater importance because of their decisive role in the drugs market and in conditions of use. Wide scale distribution of
therapeutic formularies has proved to be an effective tool and the standardization of such formularies throughout the Andean region, in the medium term, is an important step towards integration. However, prescribers' support for the essential drugs policies and the use of generic names will be crucial, so a resolute action to inform, persuade and educate is needed.

Health personnel (physicians, nurses, auxiliaries, pharmacists, and especially health promoters) are a group whose appropriate training has tremendous potential both for improving access to drugs (especially in remote or urban fringe areas) and for optimising their use. Action here should include the reform of undergraduate curricula, the development of postgraduate programmes in clinical pharmacy and pharmacology, and the design of mechanisms for continuing education. Innovative mechanisms of formal education, such as in-service training and continuous education, deserve dissemination and support. Pharmacists have a particularly relevant role to play in drug manufacture (especially regarding quality), and their professional expertise merits support from the state. There is also increasing focus on promoting the better integration and use of pharmacists within the health services (in pharmacy and therapeutic committees, purchasing committees and hospital pharmacy services), in the dispensing of drugs, in information centres and in regulatory activities, thus broadening their health-related professional scope.

Pharmacies deserve special mention. Training of pharmacy staff, especially on the risks of certain unauthorised prescribing practices and on the commercial advantages of providing genuine pharmaceutical services, has enormous potential for correcting the present shortcomings in the use of drugs. It is also important to win the support of pharmacists for the essential drugs and generic drug policies, and since these policies can benefit pharmacies by reducing stocks, rationalising the range of products and providing a better service for consumers, whenever possible, the presence of a professional pharmacist in the pharmacy should be mandatory.

In the next step of promoting public awareness of the essential drugs policies, importers also have a role to play that affects the state. This relates partly to the advisability of agreeing on a rational supply, but more particularly to promotion and advertising practices, that are of critical importance in determining conditions of prescription and use. Evidence of inaccurate and inappropriate marketing by manufacturers and retailers has led the countries of the region to adopt ethical criteria on the promotion of drugs, but there is an urgent need to seek mechanisms for their practical implementation and to find better control measures.

The role of the consumer organizations in this field is vital. The creation or strengthening of such organizations is highly beneficial, not only because of their natural role of keeping a watch on the marketing, advertising and use of drugs, but because of their experience and skills in the design and implementation of mass education campaigns, an area where they are excellent allies of the health authorities.

Drug information centres have an extremely useful role in rationalising the use of drugs, because they are able to supply timely, objective, reliable and relevant data on specific aspects of drugs (toxicity, most suitable dosages, interactions, side effects, etc.). Health ministries have the task of promoting such centres at the national level and forming an Andean network of drug information centres.

Some countries have experience of pharmacy and therapeutic committees within the service-providing institutions and have benefited from the initiative and participation of prescribers, dispensers, pharmacists, managers and consumer organizations. These committees review prescribing practices and endeavour to track progress towards rational prescribing; they also draw up and revise the institutional or local therapeutic formularies and identify the sources of irrationality. While their aims are basically health-related, they make a positive contribution to improving the use of drugs, and to rationalising purchasing.

The countries of the Andean region are beginning to carry out epidemiological surveillance programmes and studies on the use of drugs. Many are conducted on the initiative of the consumer organizations and tend to highlight the aspect of irrationality in use (inadequate prescribing, illegal sale of prescription drugs by the retailer, inappropriate self-medication) and non-compliance with the prescription. As yet, only a few studies relate to the investigation of side effects. It is most important to promote all these initiatives.

The undeniable existence of curative alternatives to modern pharmaceuticals makes it necessary to seek ways of incorporating these alternatives in the health services. Greater attention should be paid to research on medicinal plants and on the influence of culture on the perception of disease and drugs, especially among indigenous groups.

Industrial development

Essential drugs and generic drugs policies make an important contribution to conquering new and wider markets in a region where governments and manufacturers are allied. Industrial complementarity, new possibilities for the transfer of technology and the development of a pharmaceutical and biotechnology industry are more feasible within an Andean market. The universities have an important role to play in the development of technology in the pharmaceutical sector.

Governments should seek mechanisms for guaranteeing the availability of essential products of low commercial interest (such as certain biologics).

Andean integration

During the last three years, with the support of the World Health Organization/Pan American Health Organization and the Hiplito Umana Agreement, some important technical instruments have been agreed upon for setting up a joint pharmaceutical market which gives priority to meeting health criteria. This work has entailed a continuous process of discussion, reflection and refinement, in which continuity of the technical human resource input has been essential. The joint experience gained has led to the necessary consensus and commitment to take practical action to implement the agreements. These include the harmonisation of registration criteria; of essential drug lists; of pharmacological standards; of good manufacturing practices; and the creation of the Andean Review Board and the Andean Quality Certificate.

Such proposals require political support, collaboration with the economic sectors, and detailed drafting and negotiation, to which the representatives of the Andean countries present at this meeting can make a commitment in the form of a timetable of short-, medium- and long-term activities.

1) Within the framework of Andean health cooperation, based on the Declaration of Curacaya (May 1991) and subsequently in Sanofi de Bogotá, Quito, La Paz and Villa de Leyva, the five countries have discussed and proposed criteria for the harmonisation of policies, health registration, quality control, basic frameworks, pharmacological standards and technical components for international trade. A considerable degree of progress has been made towards the early implementation of these criteria.

2) WHO-PAMU. ( Policies on the authorisation of pharmaceutical products), Document of the meeting of experts of the Andean subregion, Quito, Ecuador, December 1992.


4) Translator's clarification: No international non-proprietary name (INN) is given.

5) Special agreement on health issues within the Andean Common Market.
Kenya: updating the Essential Drugs List

Kenya was one of the first countries to recognise the importance of the essential drugs concept, and in 1981 made its own essential drugs list, based on the WHO model list. The Kenya list was for all levels of health care but was initially used for the rural health institutions and also formed the basis of the monthly drug kits to rural facilities. All drugs in the public sector were supplied through the Medical Stores Coordinating Unit, with Kenya's Essential Drugs Programme undertaking coordination, field supervision and training. In the late 1980s the Ministry of Health promoted the list at the secondary and tertiary health care facilities. But although the list had prioritised the drugs that were to be procured and distributed, it was not strictly adhered to and problems in drug supply and management continued.

In the early nineties drug shortages were exacerbated by serious problems in the Kenyan economy. Apart from a general decline in the availability of public funds, the Kenya shilling had lost 50% of its value against the US dollar and inflation had increased markedly. This inevitably increased the price of imported drugs, sometimes by 80%, with importers raising prices in anticipation of the inflation. In this difficult situation the Ministry of Health (MOH) decided in 1992 to intensify its focus on rationalising the pharmaceutical sector. Part of this approach was to update the national list of essential drugs and to rigorously implement the revised list as the basis for managing drug supply in the public sector. Rational drug use would also be targeted through the development of clinical treatment guidelines.

Preparatory work in tandem

The review of the essential drugs list was started by preparing a computer worksheet listing the drugs from the 1981 national list, the most recent (1992) WHO model list of essential drugs and those mentioned in draft clinical guidelines. The main principle was that national treatment guidelines for the most common diseases and complaints, rather than the existing lists of drugs, were to be taken as the starting point. It was decided that the draft list would be reviewed at a national workshop, to be sponsored by WHO's Action Programme on Essential Drugs. The Ministry of Health, with support from the USAID-assisted Kenya Health Care Financing Project (KHCFP), had been developing clinical guidelines for use in the public sector hospitals. After consultations with university teachers and specialists in provincial hospitals a draft was prepared and distributed widely for comments. KHCFP was sponsoring a workshop to finalise the guidelines. It was then decided to hold the two workshops simultaneously and in the same location, in May 1993. In this way there could be interaction between the two groups and a joint meeting of all participants could be held on the final day to complete the essential drugs list. This would ensure that the selection of essential drugs would match the final treatment guidelines.

Table 2: Kenya Essential Drugs List by Levels of Care

<table>
<thead>
<tr>
<th>Level of Care</th>
<th>Specific Drugs</th>
<th>Strengths and Dose Forms</th>
</tr>
</thead>
<tbody>
<tr>
<td>Referral - Kenya National Hospital</td>
<td>100</td>
<td>256</td>
</tr>
<tr>
<td>Provincial general hospitals</td>
<td>100</td>
<td>256</td>
</tr>
<tr>
<td>District hospitals</td>
<td>171</td>
<td>223</td>
</tr>
<tr>
<td>Sub-district hospitals</td>
<td>136</td>
<td>126</td>
</tr>
<tr>
<td>Health centres</td>
<td>57</td>
<td>75</td>
</tr>
<tr>
<td>Community health workers</td>
<td>43</td>
<td>57</td>
</tr>
</tbody>
</table>

Essential drugs list workshop

The participants were mainly government pharmacists from different departments of the MOH. They were joined by a professor of clinical pharmacology and a clinical pharmacist from the University of Nairobi, a senior nursing officer and the head of the Kenya Essential Drugs Programme. Although there was only one local clinician in this group, the input from the draft clinical guidelines and the final session with the clinicians from the clinical guidelines workshop ensured that the essential drugs list was in keeping with national clinical practice.

The group based its deliberations on the WHO definition and criteria of essential drugs (Table 1). The emphasis was on drugs that were necessary for the health care needs of the majority of the population. This point was well taken, since during each debate over a particular drug a participant invariably asked: "Does it benefit the vast majority of the people?" The list was divided into seven levels of care. Table 2 lists the number of drugs in each of the seven levels, while Table 3 shows an example of the permitted use of injectable antibiotics at each level.

Some categories of drugs represented a special problem, e.g. antidepressants. On the one hand, few would benefit the vast majority of the population. On the other hand, when needed in a rare emergency, they could be life saving. But this implied that the drugs available at all levels of health care, including the lower ones. Initially the group deleted most antidepressants, but reinstated them in later discussions.

The group adhered to generic names, and focused on cost, especially with regard to patented products - and trying

Table 1: WHO Criteria for the Selection of Essential Drugs

- Essential drugs are those that satisfy the health care needs of the majority of the population. They should be available at all times in adequate amounts and in the appropriate dosage form.
- The choice of drugs depends on many factors, such as the pattern of prevalent diseases; the treatment facilities; the training and experience of the available personnel; the financial resources and general demographic and environmental factors.
- Only those drugs should be selected for which sound and adequate data on efficacy and safety are available from clinical studies and for which evidence of performance in general use in a variety of medical settings has been obtained.
- Each selected drug must be available in a form in which adequate quality, including bioavailability, can be ensured, in variability under the anticipated conditions of storage and use must be established.
- Where two or more drugs appear to be similar in the above respects, the choice should be made on the basis of a careful evaluation of their relative efficacy, safety, quality, price and availability. In cost comparisons between drugs, the cost of the total treatment, not only the unit cost of the drug, must be considered. The cost-benefit ratio is a major consideration in the choice of some drugs for the list. In some cases the choice may also be influenced by other factors, such as comparative pharmacokinetic properties, or by local considerations such as the availability of facilities for manufacture or storage.

Essential drugs should be formulated as single compounds. Fixed-ratio combination products are acceptable only when the dosage of each ingredient meets the requirements of a defined population group and when the combination has a proven advantage over single compounds administered separately in therapeutic effect, safety, or compliance.
most such drugs were deleted as facilities for drug information were limited. The wide dissemination of the updated data and guidelines must encourage the provision of such information in the future.

Drugs on the essential drugs list are, by definition, considered as priority drugs (primary schedule). However, the group also defined criteria for procuring drugs as enlisted in the list (Table 4), which is possible through the pharmacy and therapeutics committees in hospitals. These drugs are classified as secondary schedule or primary drugs. Moving drugs to the secondary schedule was a satisfactory compromise when a participant argued strongly for a particular drug to be included in the essential drugs list.

The draft list prepared for the final joint session of the two workshops contained fewer drugs than the 1981 version. The contribution of the specialists from the clinical guidelines workshop was highly pragmatic and led more to the deletion than to the addition of drugs.

The final list now contains the therapeutic category, generic name, dosage form, strength and pack size of each drug, and stipulates that the specifications of these drugs shall be British Pharmacopoeia, unless otherwise stated. In the past there have been problems with tender specifications. Pack sizes have not been specified and tenders were awarded to the lowest bidder, although the pack size was smaller, resulting in a higher total price. In one tender for paromomomicotrimoxa, the offer of monopropionate sodium succinate was the cheapest and was accepted. However, it is required a special drug which was not included in the price. This brought the final cost to more than the highest quotation that had been submitted. The precise specifications of the products to be procured by the MoH in the updated list, should help avoid some of the problems encountered in the past and also facilitate local manufacture.

The printed list, a 28-page booklet which includes background information, selection criteria, and listings by therapeutic category, level of care and an alphabetical listing with MSCU codes, is distributed to all public sector hospitals, missions, the professional associations, and local manufacturers.

Use of the list

In the new National Drug Policy for Kenya, which was adopted in September 1993, it is explicitly stated that the essential drugs list will be used for the following purposes:

- Public education and information
- Public sector procurement, prescribing and dispensing
- Paramedical and medical graduate education
- In-service training programmes for health professionals
- Preferential import duties and value-added taxes on drugs
- Selective support for the local pharmaceutical industry
- Drug policies
- Controlling drug donations.

Revision of the EDL

The EDL is intended to be a "living list". Regular revisions are planned and the Ministry of Health recognises that the revision process will benefit greatly from the experience and recommendations of prescribers, pharmacists and scientists. To facilitate this process a revision request form has been included in the published list. The form asks the person requesting the change to provide therapeutic category, level of care and an alphabetical listing with MSCU codes, and a unit of pack, has been distributed to all public sector hospitals, missions, the professional associations, and local manufacturers.

LETTERS TO THE EDITOR

Long term use of medicines by Southern Brazilian children

Editor,

In an extensive review of drug use in developing countries no studies about long-term use of medicines by children were found yet our research has shown that in our Brazilian city at least this is clearly a problem.

We studied the use of medicines in a population-based cohort of 4,746 children in Pelotas, Southern Brazil in 1986. In the first follow-up, when the children were aged 3–4 years, 55.8% of the mothers reported use of one or more drugs during the previous two-week period. 9.5% of the children had taken a medicine daily for one month or more.

This striking pattern of long-term use of medicines at an early age in children with chronic health problems is uncommon seen in largescale studies. The most common drugs were combinations of vitamins and mineral supplements (36.5%), antibiotics (11.5%), ferrous sulphate (4.9%), phenobarbital (4.4%) and theophylline (2.5%). The main reasons for use were loss of appetite (31.4%), anaemia (9.5%), weakness (9.5%), convulsion (7%) and asthma (6.2%). Doctors were responsible for the prescription of 84.5% of drugs taken for one month or more.

The consequences of such widespread and apparently irrational use of medicines in children are potentially grave. The availability of a large number of medicines in the home may be a risk for drug poisoning in children. Another concern is that long-term drug use could lead to medicine- or drug addiction. The heavy economic burden on the family income represented by such drug consumption over extended periods is also an important issue. The price of antibiotic stimulants, for instance, is similar to that of ampicillin (considered an expensive medicine). The monthly cost of a treatment with the most expensive antibiotic stimulant in the market amounts to 12% of the minimum wage (1.00 M - US$50). It is difficult to understand why well nourished children (malnourished children were not associated with long-term use of medicines) were treated by doctors with medicines for "loss of appetite syndrome".

Inadequate training of doctors in therapeutics and in recognising situations where psychological and social problems are relevant are evidently contributing factors to this apparent poor practice.

Stricter government control over irrational pharmaceuticals marketed in the country could play an important role in tackling the problem. The Brazilian Government recently banned several antibiotic stimulants from the market. However, the pharmaceutical companies appealed the decision in court and began selling the products again.

Long-term use of drugs by children seems to be a neglected subject in medicine utilisation research and should be more widely investigated. Our study indicates a serious problem and the need for more awareness and action by both the health services and health professionals.

In 1993 we began a new cohort study, on the use of medicines for babies. Preliminary results on long-term medicine use in children under three months show that the prevalence in this group is even higher than that in the older children of the previous study.

REFERENCES


Jorge Umberto Rébio, Departamento de Medicina Social, Faculdade de Medicina, Universidade Federal de Pelotas, Caixa Postal, 464 - CEP 96.010-150 Pelotas, RS, Brazil.

This is a thought-provoking presentation of major themes and issues in the continuing effort to improve the use of medicines in Australia, which is generally viewed as an innovator in the area of medicines education and information programmes for consumers. The conference brought together consumer, government, providor and pharmaceutical industry representatives to discuss the wise use of medicines. A major theme of the conference was that patients should not be viewed simply as passive receivers of advice and information but as potential educators of health officials and researchers. Snapshots of education and information campaigns in Australia are given, including a community-based asthma control programme and a patient education campaign on managing diabetes. This publication also reports on conference sessions covering consumer initiated research, how to finance and evaluate research projects, focus groups, teamwork and partnership.

Available from: Department of Health, Housing, Local Government and Community Services, P.O. Box 984A, Canberra, ACT, 2601, Australia.


A well-illustrated guide for those responsible for planning and organizing pharmacetical purchasing at national and regional levels, this manual describes the technical procedure for store sizing and sets it within the broader context of drug purchasing, inventory control and stock administration. There are sections on calculating volumes, including transport volumes, and on recording data, together with details of environmental requirements, fire and security precautions. Although the book is not intended as a warehouse design guide it includes a short section on building design.


Today, 40 years after the introduction of chemotherapy for tuberculosis, there are more cases (8 million per year) than ever. Mycobacterium tuberculosis kills 2.0 million people. Today, probably more than any other single infectious pathogen. In developing countries, where approximately 95% of these cases occur, care rates remain unacceptably low and transmission has increased as patients form an increasing reservoir of infection. In addition, the spread of human immunodeficiency virus (HIV) infection has contributed to the growing number of tuberculous cases worldwide.

The guidelines in this book, which are based on experience gained in successful tuberculosis-control programmes throughout the world, are intended to assist people responsible for running national tuberculosis programmes in establishing effective, standardized short-course chemotherapeutic regimens for the disease. The currently recommended treatment regimens for the various categories of patients are described, together with alternative regimens suitable for use in those who are HIV-positive. Other programme issues, including monitoring of patients, evaluation of the programme, quality assurance of drugs, and costs of the recommended treatment regimens, are also discussed.

Available in English (French and Spanish in preparation) from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price SwFr 14,00CHLS. and in developing countries SwFr 5,50.

How to estimate warehouse space for drugs


The vast range of indigenous, tribal folklore and traditional systems of medicine, part of the heritage of most Asian countries, still needs to be adequately explored. Although herbal medicines are already extensively used in these countries, the potential for their wider use in primary health care and in modern systems of medicine have been largely unrealised, as has the potential for discoveries of new medicines from these plants. Only now, after years of relative lack of interest, are pharmaceutical companies showing interest in supporting research to discover new medicines from plants, argues the author of this thought provoking publication.

Western countries are now using herbal remedies more and more to increase their use within a regulatory framework. Asian and African countries want to utilise the herbs and plants, which have long proved their efficacy and safety, even more effectively in their primary health care systems. The author suggests how many of the issues relating to research, clinical evaluation, standardisation and regulation, could be tackled over the next two decades to ensure that we derive as much benefit as possible from our herbal wealth. This book should be of interest to researchers, health administrators, regulatory bodies, primary health care practitioners and organizations interested in traditional medicines.

Available from: WHO Regional Office for South-East Asia, World Health House, Indraprastha Estate, New Delhi 110002, India.
Essential Drugs Monitor

PUBLISHED LATER


This text provides a basic introduction to the principles, methods and applications of epidemiology in medicine and public health. Intended for use in a formal training course, the book also aims to stimulate an appreciation for the approach to health care that is increasingly concerned with preventive medicine and the most efficient use of health resources. To this end, the authors use numerous examples from the scientific literature to show how the tools of epidemiology can be applied to the prevention of disease, the promotion of health, and the formulation of national policies. Particular attention is given to the use of epidemiological research to detect associations between modifiable environmental exposures and specific diseases. By illustrating some of the discipline’s past achievements, the book also aims to stimulate appreciation for the wide-ranging contribution that epidemiology can make to health care and public health policy.

Each chapter concludes with a series of study questions designed to get students thinking in an exemplary way. Answers to the study questions are annexed to the text. The book is complemented by a "Teacher’s Guide", which offers advice on the organization of the course and provides illustrations suitable for overhead projection.

Available in English (French and Spanish in preparation) from: World Health Organization, Distribution and Sales, 2111 Geneva 27, Switzerland. Price Sw.Fr. 18/US$16.20, and in developing countries Sw.Fr.12.50.


There is considerable trade in herbal medicines among the Asian countries of Indonesia, Thailand, the Philippines, Malaysia, Singapore and Brunei Darussalam, and some of them have initiated programmes to promote the use of herbal medicines in primary health care. Further progress is being hampered, however, by the lack of safety and efficacy studies and deficiencies in the standardization procedures for these medicines. Problems include premature harvesting, caused by a shortage of supply or supply local demand, resulting in substandard, crude drugs. These are then adulterated with chemical substances to boost their effect. There are also possible risks because local names can refer to more than one plant.

This publication aims to encourage regional herbal medicine producers to comply with specifications on crude drugs, in order to ensure the safety and quality of herbal medicines.

Plants are listed using their traditional, national and English names, with their description, geographical distribution, habitat, chemical constituents, chemical identification tests and quality specifications.

Available from: The Association of South East Asian Nations, P O Box 2072, Julien Tuman Pajemban 6, Jakarta, Indonesia.


When Problem Drugs was first published in 1986 it met with wide acclaim. Typical recent endorsements include: "it is great that it is available in the information which cannot be obtained from manufacturers". (Tasmanian Bureau of Standards). "The recommendations are generally clear, entirely acceptable and obviously necessary." (The Lancet). "Its findings, particularly as regards to the developing countries, are disquieting." (British Medical Journal). "Health educators love it!" (National Rehabilitation Bureau [Uganda]) and "Essentially and thought provoking reading" (Nursing Times). Since then it has been widely translated by means of thousands of health workers, pharmacists, policy makers, opinion leaders, researchers, facilitators, and health professionals around the world.

This second edition builds on and updates the earlier work and includes revisions based on a user survey.

One great strength of the book, and probably the reason it has been so extensively drawn on, is the accessibility of the material, which combines user friendliness with extensive referencing. It is valuable also in that it rightly places the issues surrounding specific “problem drugs” in the broader public health and societal context. Also, Andrew Chotley’s introduction is unambiguous. It is tempting to focus only on those drugs that carry obvious risks”, he says, “doing so, creates the misconception that these few substances are the problem and that if they are dealt with, we will be left with a selection of medicines that are of high quality, meet real health needs, and are effective and affordable. Unfortunately this is not the case”, he continues. “As the many examples in this pack demonstrate, the problem is not a few hazardous drugs promoted by one or two wayward companies in the pharmaceutical industry. It is an inevitable result of the ways in which the pharmaceutical industry is structured and operates. What makes a drug a problem is not so much its inherent pharmacological risks, but the way it is priced, promoted and used.” Chotley emphasizes that “it is impossible to talk about the “safety” of medicine as if it was a laboratory problem. In the wrong hands and at the wrong time even the most carefully quality controlled medicine becomes transformed from a life saver to a life threatener. In some cases (male infertility, antibiotics), the consequences stretch beyond a single patient or group of patients, to encompass the globe”, he concludes.

The pack contains detailed information on what it describes as “problem drugs”, together with recommendations for campaign action by Health Action International groups in more than 50 countries. Topics covered include drugs and children and the elderly; antidepressants; antibiotics; anabolic steroids; cough and cold remedies; growth stimulators; drugs in pregnancy; contraceptives: hormone replacement therapy; and psychotropics. The pack may very well become the go to the issue of women and drugs. Although, as it highlights, women are both the major users and major purveyors of health care, they are seldom in a position to determine the priorities. Most health care systems are male dominated in terms of policy and decision making and effectively exclude women from positions of power. The model of a male life cycle is too often taken as a norm. This has the paradoxical effect that on one hand a huge number of natural and normal processes become diagnosed as “abnormal” and as a result requiring medicines, while on the other hand, women are often under represented, if not totally ignored, in critically important research on the outcomes of different treatment strategies.

In general, the author argues that stronger controls on promotion are needed, and that prescribers and consumers should have greater access to independent drug information. The many specific demands include a call for more research into the effects of drugs on women, full governmental reviews of all cough and cold preparations, and the introduction of licensing restrictions and advertising controls on products such as appetite stimulants, brain tonics and anabolic steroids.

Available from: HA-Europe, Jacob van Lempkade 1.44E, 1053 SD Amsterdam, The Netherland, Price: Dfl. 30 + Dfl.5 for postage and handling.


Approximately 103 of global public sector funding for contraceptive research is devoted to immunological contraceptives but this research should stop, according to a new study which highlights the serious risks to women’s health and reproductive rights.

Vaccination Against Pregnancy: Miracle or Menace? just published the results of research on immunological contraceptives. This preventive approach, causing the immune system to attack a body substance which is essential for reproduction, which is the most advanced research method, is currently evaluated for use in early pregnancy. The aim is to create an injectable contraceptive which is effective for five to ten years, but, states the author, during this time there is no way to reverse the contraceptive effect.

Tests have already been conducted on women in India, Finland, the Dominican Republic, Chile and Brazil and will soon begin in Sweden, and researchers believe a product will be ready for marketing in five to ten years.

The author points out that many women’s organizations have already voiced their concern about the potential for abuse because immunological contraceptives are long acting and given by injection. The author states that the method is based on tricking the body into attacking part of reproduction as it would attack a pathogen, and says that this type of reaction would normally be considered an autoimmune disease. According to the author the long-term health risks for women and for children accidentally exposed before birth are unknown, as are the risks if users become HIV positive or develop AIDS. The study concludes that unless concerns about safety, effectiveness, privacy, reversibility and potential for abuse can be met, this research should not be continued.

Available from: HA-Europe, Jacob van Lempkade 1.44E, 1053 SD Amsterdam, The Netherlands, Price: Dfl. 14.5 + Dfl.5 for postage and handling.

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RESEARCH

Results of drug use survey in Bangladesh

In June 1982 Bangladesh introduced a national drug policy (NDP) and drugs ordinance in accordance with WHO guidelines on the selection of essential drugs (see EDM-15). Since the enactment of the NDP, the availability of essential drugs as well as their production and quality have significantly increased. Although doctors’ consultations most commonly result in drugs being prescribed, very little is known about whether drugs are appropriately used.

The Community Medicine and Pharmacology Departments of four medical colleges - Chittagong, Khulna, Mymensingh and Rajshahi - therefore conducted a survey in November 1992 to assess patterns of drug use for six common diseases in the public sector, at the primary health care level. The six diseases were: watery diarrhoea, dysentery with blood, helminthiasis, pneumonia, acute respiratory tract infections and scabies. Data on the availability of essential drugs were also collected.

Ten thana health complexes (THCs) and 10 union sub-centres (USCs) were randomly selected in each division, totalling 80 facilities country-wide. In each facility, data were collected from registers (36 cases) and by observation (36 consultations and 36 dispensing).

Results showed that the average consultation time - 54 seconds - was low. At THCs, consultation time averaged 60 seconds and at USCs, 48 seconds, both of which are very unsatisfactory.

Only 37% of the patients were adequately examined, 41% at THCs and 25% at USCs. At the THCs, where the health professionals are medical doctors, the quality of care in terms of time spent with the patient and adequate examination is a slight improvement on USCs, where the prescribers are medical assistants. However, the quality of care in general is unsatisfactory, at both levels. These results question the appropriateness of the diagnosis made.

Only 41% of patients received adequate treatment in accordance with standard treatment guidelines. This is a disturbing finding which is similar for THCs (43%) and USCs (39%). In general, the number of drugs prescribed was satisfactory (1.44 drugs per patient), with doctors at THC level prescribing less (1.4) than medical assistants at USCs (1.48). 25% of patients were treated with antibiotics, which is relatively low compared with results from studies conducted in other countries. There is no statistical difference between THCs (25%) and USCs (24%). Similarly there is no statistical difference between the rates of metronidazole in THCs (15%) and USCs (18%). The use of metronidazole is high for all tracer diagnoses (17%), particularly since some required metronidazole as treatment. Doctors and medical assistants have similar prescribing patterns.

The survey found that 78% of drugs were prescribed by generic name and 85% were from the essential drugs list (see Table 1). These results are good and probably arise from the implementation of the National Drug Policy.

In contrast, the availability of the 12 drugs under review was low (54%); being lower for USCs (46%) than THCs (63%), which directly affects prescribing patterns. Financial constraints reportedly limit the drug supply, but even within these constraints drug availability could be increased through improved management.

Dispensing time was extremely short at 53 seconds and no disparity was found between THCs and USCs. The short dispensing and consultation times may explain why only 55% of patients know how and when to take the prescribed drugs. In fact even lower knowledge might be expected; but the limited number of drugs prescribed may explain why patient knowledge is relatively high.

The percentage of drugs dispensed in accordance with the prescription was 84%. This finding is acceptable but should be considered with caution since the medicines are often prescribed on the basis of whatever supplies are available at the health centre on that day, rather than therapeutic suitability. Most of the prescribers have a current list of what is available.

Because of the large sample size - 80 facilities - and the low variability of the results, the findings can be considered representative of the overall situation of drug use in rural Bangladesh. The deficiencies identified in the survey are of critical importance to improving the rational use of drugs, and will serve as a basis for targeting and evaluating future interventions undertaken by the Improvement of Drug Management Project.

Table 1: Drug use pattern in out-patient departments

<table>
<thead>
<tr>
<th></th>
<th>THC</th>
<th>USC</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average number of drugs prescribed per patient</td>
<td>1.44</td>
<td>1.48</td>
<td>1.40</td>
</tr>
<tr>
<td>Patients receiving antibiotics %</td>
<td>25</td>
<td>24</td>
<td>24</td>
</tr>
<tr>
<td>Patients prescribed metronidazole %</td>
<td>15</td>
<td>18</td>
<td>17</td>
</tr>
<tr>
<td>Drugs prescribed in generic names %</td>
<td>77</td>
<td>78</td>
<td>78</td>
</tr>
<tr>
<td>Drugs prescribed from essential drugs list %</td>
<td>89</td>
<td>82</td>
<td>85</td>
</tr>
<tr>
<td>Patients treated according to defined standard %</td>
<td>43</td>
<td>39</td>
<td>41</td>
</tr>
</tbody>
</table>

Table 2: Quality of care regarding consultation and dispensing of drugs

<table>
<thead>
<tr>
<th></th>
<th>THC</th>
<th>USC</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Average consultation time per patient (seconds)</td>
<td>69</td>
<td>48</td>
<td>54</td>
</tr>
<tr>
<td>Patients receiving an adequate examination</td>
<td>41</td>
<td>32</td>
<td>37</td>
</tr>
<tr>
<td>Average dispensing time per patient (seconds)</td>
<td>23</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>Drugs dispensed according to prescription %</td>
<td>80</td>
<td>82</td>
<td>81</td>
</tr>
<tr>
<td>Patients with adequate knowledge about their dispensed drugs %</td>
<td>80</td>
<td>82</td>
<td>81</td>
</tr>
</tbody>
</table>

Table 3: Availability of essential drugs and ED list

<table>
<thead>
<tr>
<th></th>
<th>THC</th>
<th>USC</th>
<th>Average</th>
</tr>
</thead>
<tbody>
<tr>
<td>Availability of 12 essential drugs %</td>
<td>63</td>
<td>46</td>
<td>54</td>
</tr>
<tr>
<td>Presence of the national essential drugs list %</td>
<td>28</td>
<td>9</td>
<td>16</td>
</tr>
</tbody>
</table>

* The survey was coordinated by the Improvement of Essential Drug Management at the PHC Level Project, assisted by UNICEF and members of the International Network for the Rational Use of Drugs in Bangladesh (INURED).

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