Essential Drugs Monitor

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Essential Drugs Monitor

The Essential Drugs Monitor is produced and distributed by the WHO Action Programme on Essential Drugs. It is published in English, French, Spanish and Russian, and has a global readership of some 200,000 to whom it is free of charge. The Monitor carries news of developments in national drug policies, therapeutic guidelines, current pharmaceutical issues, educational strategies and operational research.

WHO's Action Programme on Essential Drugs was established in 1981 to provide operational support to countries in the development of national drug policies and to work towards the rational use of drugs. The Programme seeks to ensure that all people, wherever they may be, are able to obtain the drugs they need at the lowest possible price; that these drugs are safe and effective; and that they are prescribed and used rationally.

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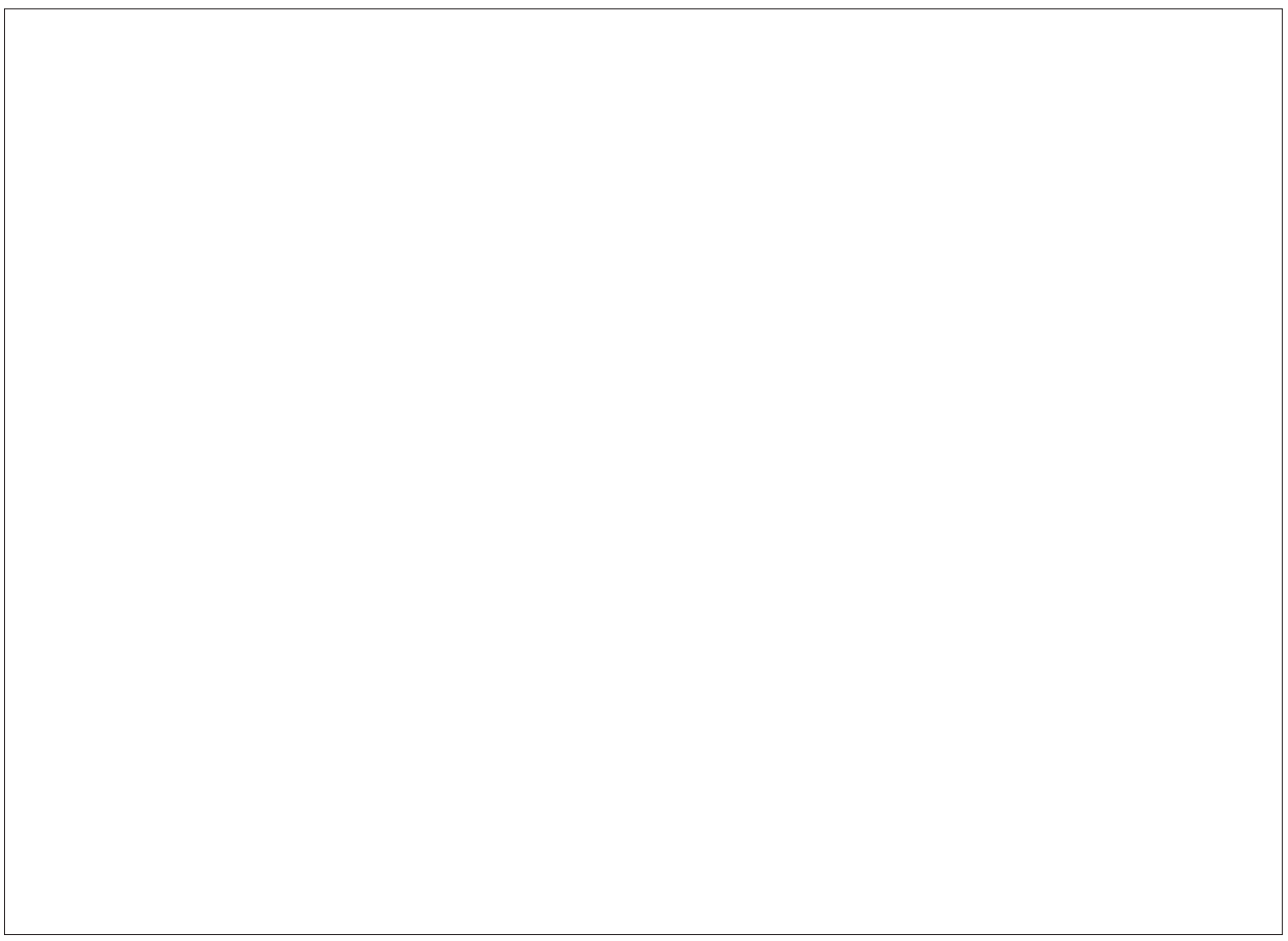
Getting the BEST from drug donations



Picture of a disaster as seen by one Russian boy, Mark Pogosyan

EDITORIAL

MEDICINES play an important part in international humanitarian relief efforts, and drug donations can take many forms. They may be channelled through aid agencies in emergency situations or be included by governments in development aid. They may be sent from groups of concerned individuals or NGOs with regular links to the developing world. Drug donations may also have a commercial face; used by companies to obtain tax deductions on unused stock or create a later market for certain products.

In most cases the individuals and organizations involved see donations as tangible expressions of concern and solidarity with people in need. But despite good intentions, experience over the years shows that some drug donations can be more harmful than helpful. They may not be relevant for the emergency situation, for the disease pattern or for the level of care that is available; they may even be dangerous. They may be unknown to local health professionals and patients and may not comply with local drug policies or standard treatment guidelines. Many donated drugs arrive unsorted, or without an international nonproprietary (generic) name on the label. When this occurs, scarce resources are wasted and people in need continue to suffer.

There are several underlying reasons for these problems. Probably the most important is the common but mistaken belief that where there is a scarcity of drugs any type of drug is better than none at all. Another is a lack of communication between donor and recipient, so that needs and local resources are not properly determined. Donating drugs is a complicated process in which donor and recipient need to cooperate in order to ensure that the donation is useful.

In order to help both donors and recipients to maximise the potential benefits of drug donations, WHO has been working with the major international relief agencies (UNHCR, UNICEF, ICRC, IFRCRCS, MSF, CMC and OXFAM) to develop interagency guidelines. These were finalised and formally endorsed in April l996, and are reproduced in full in this issue. The guidelines build on earlier work by the International Committee of the Red Cross and the Christian Medical Commission of the World Council of Churches. They reflect not only an interagency consensus but also consultations with over 100 humanitarian organizations and individual experts.

The guidelines are based on four core principles: l) a drug donation should benefit the recipient to the maximum extent possible; 2) a donation should respect the wishes and authority of the recipient, and support existing government policies; 3) there should be no double standards in quality – if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation; and 4) there should be effective communication between the donor and the recipient.

Much has been written about the problems and extent of inappropriate drug donations. But in highlighting and tackling these it is also important not to lose sight of the many donations which have met critical needs in time of crisis and shortage. The new guidelines are intended to encourage and facilitate this work and to help both donors and recipients make sure that they really get the best out of the resources expended. The use of the guidelines will be monitored and they will be reviewed after one year's experience to determine any areas in which they need to be strengthened or modified. ❑

PUBLIC EDUCATION

Consumers and drugs in Poland

Barbara Mintzes*

"One can only wonder – if these drugs are ineffective, why are so many prescribed by doctors?", asked Wojciech Maselbas of the Warsaw Academy of Medicine. He was referring to a list of the most frequently used drugs in Poland, during a meeting of consumers, health workers and policy makers, held in Warsaw in September 1995.

The Polish Consumer Federation embarked on a one-year consumer education project in late 1994, so beginning work to improve the way medicines are prescribed, used and regulated in Poland. This project was co-sponsored by Health Action International (HAI-Europe) and financed by the European Union's PHARE Programme.

The Federation knew that this initiative would only be successful if it had health professionals and policy makers on its side. At first this was not an easy task. Like many countries, Poland has a conservative medical tradition based on a curative rather than a preventive approach to health care, with little consumer involvement in decisions on treatment options. "Whenever I ask my doctor questions, I feel like an intruder", said Malgorzata Niepokulczycka, President of the Consumer Federation and an outspoken advocate of consumer rights.

In the Consumer Federation's first meetings with Ministry of Health officials, and physicians and pharmacists' associations, a frequent response was, "Yes, we need independent information, but why for consumers? Doctors need information about medicines. They are the ones who are prescribing".

The Federation saw the need to build wide support as a means to an end – better consumer awareness about drugs and drug policy. However, its success in building a coalition of Government officials, health professionals, social workers, educators and consumers is in itself an important step towards better health care in Poland. A final project seminar called "Towards Rational Drug Use in Poland", was held near Warsaw in September 1995. Amid much discussion of the problems Poland faces, the overwhelming feeling was one of consensus and hope that, with such broad support from many sectors, change was possible.

The drug situation in Poland

Aggressive promotion, lack of access to independent, reliable information and a relaxed registration procedure were highlighted as problem areas at the seminar. According to Longina Lewandowska-Borowka of the Consumer Federation, "The consumer is responsible for his or her own health, but it is up to the State to create proper conditions for this to be possible".

The transition to a market economy during the last six years has brought a period of rapid change. When Janusz Szajewski began his career as a doctor soon after World War II, he described most drugs as existing, "to console rather than cure patients". If a drug could be manufactured in Poland, it was considered a good drug. There were special drugs in special pharmacies for party officials. These were not accessible to ordinary people.

The creation of the bulletin, Consumers and Drugs, is another important step in the campaign to educate the public

Given this recent history, it is no surprise that, according to Dr Kuzmierkiewicz, Under-Secretary of Health, stereotypes among consumers include the view that, "a cheap drug cannot be effective; more effective drugs are more expensive". Barbara Jendryczko, a lawyer with the Pharmacists Association described the public's inexperience with promotional materials: "Poles are not very immune to advertising. With the new market, people are bombarded with very bright, glossy images". She suggested introducing the subject of advertising into schools, to teach children a more critical attitude.

The decision to allow commercials on television and in newspapers for over-the-counter drugs has been a mistake, according to Adam Wasiewicz, Director of the Pharmaceuticals Department of the Ministry of Health. "There would be few problems if the Ministry of Health had the power of attorney", he said. "The Ministry has sent 30 notices of violation in television advertising, but no legal actions have been started. The State Prosecutors thought they were not very harmful".

One such violation mentioned by Dr Kuzmierkiewicz was a clip on the television evening news presenting a new antidepressant, fluoxetine, as "an antidote to unhappiness". The commercial source of the information was not made clear to the public. A similar mishap occurred in a doctors' gazette, in which an advertisement paid for by a manufacturer was presented as an article.

Drugs of dubious value

During 1994, 334 new drugs were introduced onto the Polish market, almost an average of one new drug a day. According to Dr Chrusciel, Chair of Pharmacotherapy of the Physicians' Chamber, "only 40 represent progress in pharmacotherapy, improving the range of drugs available".

At the same time, many older drugs of dubious value remain on the market. The Government has taken some initiatives to get rid of obsolete products. In 1991 drug registration was limited to a five-year maximum. Manufacturers must submit evidence of effectiveness and safety by 1997 or their products will be deregistered.

Last year the Ministry of Health published a negative list of 38 drugs which would no longer be reimbursed from the State budget. After an outcry by doctors and patients, they withdrew this initiative and reinstated reimbursement for these products. The problem, according to Dr Chrusciel, was that no information was provided on why drugs were included on this list. Some of the drugs had been widely used and removing them created a vacuum as no information on alternative treatments was provided.

Best-selling products irrational and harmful

Monika Skrzypiec of the Polish Consumer Federation compiled a list of the 20 most-sold drugs in Poland during 1994, based on sales data listing numbers of packages sold. During the September seminar, participating pharmacologists rapidly assessed the 20 best-selling products. They found 14 of the 20 to be irrational, ineffective, and potentially harmful, and felt the remaining six should not have been used as frequently as sales data suggested. "We would simply like to change this list and ensure that when it comes to the most frequently sold drugs in Poland, we will have the most dangerous drugs removed", said Monika Skrzypiec.

Drug dependency among older women

Grazyna Swiatkiewicz of the Warsaw Institute of Psychology and Neurobiology described the overuse of benzodiazepine tranquillisers and painkillers by older women. Over the age of 35, three times as many women as men are hospitalised in Poland for drug dependency. Swiatkiewicz and her colleagues carried out a questionnaire survey of a random sample of women aged 35–65: 25% had used benzodiazepines within the last 12 months. As women became older, they were more likely to use sedatives and sleeping pills. Poorer and less educated women were also more likely to use these drugs.

Similar studies have been carried out in Norway. The rate of sedative use was similar among women aged 45 and over, but many more Polish women between 35 and 45 use sedatives, 22% versus 12% in Norway. Swiatkiewicz suggested that the economic and social stresses caused by the rapid transition to a market economy may be a contributory factor.

As a result of this survey the Institute of Psychology is producing a booklet for doctors on rational use of benzodiazepines. They have also mounted a media campaign to inform the public, and especially older women, of alternative ways to deal with anxiety and insomnia and of the risks of dependency with long-term benzodiazepine use.

What information do Polish consumers want?

The Consumer Federation surveyed consumers to identify priorities for public educational materials. It planned to produce a Polish version of "Med-Sense", a pill-box first produced by Health Action International which contains 12 leaflets on drug issues. The Consumer Federation wanted to include issues of greatest importance to Polish consumers, and to identify these carried out the survey in eight cities: Warsaw, Lodz, Gdansk, Torun, Olsztyn, Jelenia Gora, Gniezno and Bytom, with the help of regional consumer clubs and researchers and students at three universities.

Respondents were asked which drugs they had used recently as well as what they wanted to know more about. One interesting finding was that people who used drugs frequently did not necessarily perceive their health as bad: although about three-quarters of people aged 18–29 said their health was good, over half had taken drugs within the last 30 days and over 70% within the last year. The survey indicated that women took medicines more often than men and that this difference was especially pronounced for over-the-counter drugs. The rate of prescription drug use was highest among the elderly.

The three most common reasons for taking drugs were: cold, flu, sore throat and cough; headaches; and rheumatic and joint pains, backache and other kinds of pain. About one-fifth of people responding had not taken any medicines in the last year.

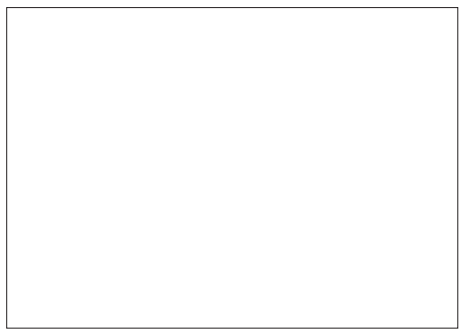
Respondents were asked to choose topics they wanted to know more about from a list provided on the questionnaire. More people picked the topic, "all drugs have side effects" than any other, a sign that Polish consumers are interested in knowing something about drug risks as well as benefits.

Med-Sens: more is not always better

"Med-Sens" (the Polish pill-box) was launched at a packed press conference in Warsaw in September 1995. The journalists all received not only a pack of Med-Sens but a proverbial "apple a day to keep the doctor away".

Med-Sens has leaflets on:

- every drug has side effects
- the essential drugs concept
- 12 questions to ask your doctor
- drug prices
- drugs and the elderly
- drugs in pregnancy
- vitamins and minerals
- analgesics
- antibiotics
- cough and cold remedies
- tranquillisers and sleeping pills
- contraceptives



"Med-Sens" has proved a great success in Poland, where consumer interest in drug issues is increasing

Seven thousand copies were printed, many more than was originally planned, because of the large amount of interest shown in the press and by regional consumer clubs. The Consumer Federation plans to print many thousands more and has been discussing financing for a second edition with the Ministry of Health.

The Consumer Federation also produced a bulletin called "Consumers and Drugs", with articles on consumer education for rational drug use, defining a problem drug, the drug market in Poland and recent problems with promotion targeting consumers. Each Member of Parliament received a copy of this bulletin.

Providing independent information for doctors

The balance of information for doctors is heavily weighted towards commercial information, and as one wry seminar participant said, "The biggest problem in Poland is that doctors don't know what to read". However, more and more independent information is becoming available. In 1995 the first edition of a national formulary was published. It is modelled on the British National Formulary and will be updated annually. The Pharmacy Institute produces an independent drug bulletin for doctors. Courses in pharmacotherapy at the Warsaw Academy of Medicine have begun to incorporate a problem-based approach to pharmacotherapy training, developed by WHO's Action Programme on Essential Drugs and the University of Groningen in the Netherlands, (see EDM-20)[1]. As Wojciech Maselbas said, "Teaching doctors how to prescribe rationally is part of this wide campaign which I hope will spread like a forest fire".

Plans are underway in Poland for a new national drug policy. As Dr Mazurek, Director of the Polish Drug Institute admits, "The 1991 medicines law has not been adequate to deal with problems caused by the rapid introduction of free market principles"[2].

Plans for the future

Dr Kuzmierkiewicz described the consensus among health professionals on the Consumer Federation project as something that had never been achieved before in Poland. The wide press coverage and distribution of materials have helped to raise public awareness and to promote the idea that, as Dr Chrusciel put it, "We should not bow to the great power of a pill, the assumption that there is a drug for every ailment".

It is, however, only a first step. The Consumer Federation hopes to bring Med-Sens and other educational materials into the regular school curriculum and to train teachers in principles of rational drug use. It is also looking for funds to bring in teachers from the Warsaw Academy of Medicines to train consumer advocates and nurses. Wojciech Maselbas captured the mood of a pressing need for change when he said, "In Poland, discussions take a long time. What can we do ***now*** to improve the situation?". ❑

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Eritrea: a community ORT education programme underway

Beverley Snell*

In 1993 the newly formed Pharmacists Association of Eritrea (ERIPA) held its first annual general meeting. This was combined with the "Pharmacy Week" to promote the rational use of drugs, which has now become an annual event. In 1995 Pharmacy Week focused on the appropriate management of diarrhoea with oral rehydration therapy (ORT). This theme was chosen with good reason: diarrhoea and the dehydration it causes are major contributors to child morbidity and mortality.

The campaign took eight months to plan and prepare, and included more extensive activities than in previous years, necessitating the participation of the majority of Association members. Work started with a preliminary survey, to gather some baseline data about community attitudes to the management of diarrhoea and the use of oral rehydration solution (ORS). The research included interviews with a random sample of mothers in the community and at a health centre; a review of paediatric outpatient hospital record cards; and a survey of 30 drug retail outlets. The work, undertaken by two key pharmacists – the Drug Information Pharmacist and the Chief Pharmacist from Mikane Hiwot Hospital – took five months to complete. This was because no specific funding was available and the survey had to be conducted out of normal working hours, using public transport.

The study revealed that almost all mothers had heard about ORS, but that a majority preferred other drugs as an immediate remedy for diarrhoea. Both physicians and community pharmacists tended to prescribe drugs other than ORS – mostly antibiotics – for diarrhoea. Overall, it was the literate or better informed mothers who made the best use of ORS. Using the survey findings ERIPA identified the targets for its campaign messages. If funding permits, a repeat survey is planned, to assess the campaign's impact.

ORS saves lives

ERIPA decided its main targets would be women and children, contacted through face-to-face events in Asmara, the capital, and six out of the 10 provinces. It was felt that, as the carers, women would be the most interested in the campaign. Also, unless mothers are convinced of the appropriateness of a treatment (even if it is prescribed) they may not use it.

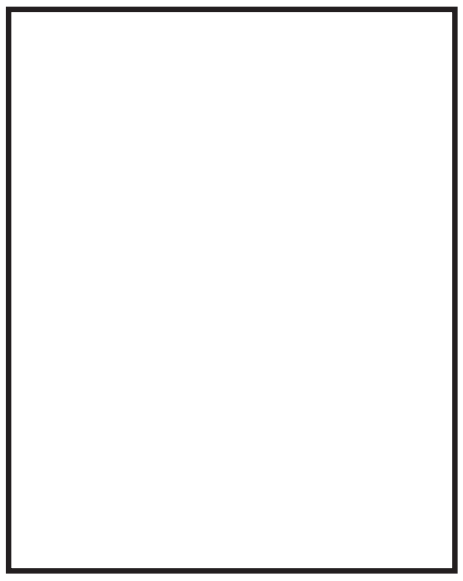
Over 15,000 sachets of ORS and 5,000 T-shirts with the logo, "ORS Saves Lives", were distributed free of charge. Banners and posters were displayed in five towns in three languages: Tigrinya (a common local language in which a large number of people are literate), Arabic and English. While these were intended to increase the visibility of the campaign, the main educational tool used was a pamphlet in Tigrinya. The pamphlet addressed the causes of diarrhoea and its appropriate management with both commercial ORS and home-prepared solutions. It explained the rationale for rehydration as opposed to other means of management, and provided detailed, well-illustrated instructions on the preparation and administration of oral rehydration mixtures. Ten thousand copies of the pamphlet were printed and distributed throughout the country.

The campaign materials were designed by pharmacist/artists experienced in the preparation of community education materials. The cost was partly covered by ERIPA with additional assistance from UNICEF and Save the Children Fund (UK).

An enthusiastic reception

The main educational strategy was interaction between pharmacists and mothers in the communities. Public meetings were organized through the municipal structures and health facilities. Mothers met in community buildings, health centre "community areas" and in open air meeting areas. The strategy proved extremely successful, attracting over 20,000 people. Some women were so keen to attend that they walked for 2 hours to reach a meeting. Men were also welcome and many came along.

ERIPA pharmacists planned the content of the presentations, and organized and allocated areas to different pharmacists. They were equipped with battery powered public address systems for outside meetings, and they carried the necessary mixing utensils and water containers. The pharmacists were responsible for the presentation and demonstration of the messages, and then called for questions from the audience. There was no shortage of questions, from both women and men, covering all aspects of diarrhoea, its treatment and features of dehydration as well as questions relating to prevention and sanitation. It was encouraging that sometimes women wanted to present the demonstration again, this time themselves, to make sure they had understood.



Eritrean pharmacists used posters to get their vital message across

Building on the campaign

Although the campaign focused on mothers, prescribers could not avoid the messages. Oral rehydration was also a focus of the ERIPA Conference associated with the Pharmacy Week, which was attended by many prescribers. The results of the survey were presented at the Conference. Examples of different educational strategies from a number of countries were also presented.

Further activities are planned to build on the campaign messages. This time school children will be important targets. One plan involves the circulation of a drama which depicts a battle over the life of a child between characters representing dehydration and oral rehydration. School children will be asked to produce this in their own way, and prize winning productions will be broadcast nationally on television. Another idea being pursued is a children's poster competition.

ERIPA's role in these community education activities shows how a national pharmacist association can play a key role in community education. ERIPA sets an excellent example of a truly professional association in which public interest more than matches the economic interests of its members. ❑

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RATIONAL USE

Zimbabwe: targets prescribing of opinion leaders

B. Trap, C. Lessing*

"If the Reverend can open the Bible many times daily without losing credibility so can we open the Essential Drugs List many times daily", said one of the specialists attending a two-day consultative meeting in Kadoma, Zimbabwe. The high level prescribers were gathered to develop national recommendations for improving rational drug use and use of the Essential Drugs List for Zimbabwe (EDLIZ) and Standard Treatment Guidelines.

Since the start of the Essential Drugs Action Programme in Zimbabwe (ZEDAP) in 1986 almost all rational drug use activities have been aimed at the primary health care level. In order to achieve rational drug use and adequate drug availability, an extensive training programme was conducted. From 1989 to 1992 more than 5,000 health workers, mainly prescribing nurses, were trained in stock management, the essential drugs concept and the use of EDLIZ. Training was also provided on the ZEDAP clinical and management modules. The impact of the training has been measured on a regular basis, with very encouraging initial results. Stock management and adherence to standard treatment guidelines improved and peaked in 1991 but later decreased[1] (see Table).

The WHO/INRUD indicators used in the impact assessment do not indicate rational drug use problems. However, more specific studies, looking at the use of antibiotics at primary health care level, found that only 22% (range 2–66%)[2] of antibiotics were used correctly (correct drug, correct dose and duration). In 24% (range 4–47%)[2] of cases, treatment with antibiotics was unnecessary. Interviews with prescribing nurses found that non adherence to standard treatment guidelines was related to behaviour, attitude and motivation and not to knowledge[3]. In addition, surveys of central and provincial hospitals found that in only 5% of cases where selected indicator drugs were prescribed was the drug chosen actually the drug of choice[4].

Table 1

Impact of training on health workers[3]

Indicator	1989	1991	1993	1995
Adherence to Standard Treatment Guidelines at all levels of health care in Zimbabwe				
• Gonorrhoea		83%	68%	50%
• Diarrhoea			48%	36%
• Acute respiratory infection		73%	60%	39%
Implementation of stock management	30%	69%	55%	41%
WHO/INRUD Indicators				
• No. of drugs per prescription	1.4	1.3	1.65	1.65
• % generic	85%	94%	92%	90%
• % antibiotics	22%	29%	30%	27%
• % injections	14%	13%	14%	13%

Based on these and other findings, the National Drug and Therapeutics Policy Advisory Committee found that the previous "bottom up" approach, based on primary health care level training, was not enough to ensure rational drug use and adherence to EDLIZ. A "top down" approach was also needed to involve higher level prescribers more directly.

In recognition of the major role consultant doctors play as trainers of future prescribers and as opinion leaders, a meeting was organized in March 1996, with consultants from all over Zimbabwe. The main aim was to confer with high level prescribers on how rational prescribing and adherence to EDLIZ could be improved.

Speakers emphasised that if Zimbabwe's limited resources were not to be depleted, rational use of drugs must have an important place in all health workers' daily work; that EDLIZ was for everyone – from health assistant to consultant; and that new approaches have to be adopted in the education of health care providers, with emphasis placed on skills more than knowledge.

On the first day discussion centred on agreeing that rational use problems actually existed amongst higher level prescribers and that the standard treatment guidelines in EDLIZ were also made for specialists to follow. The problems identified were then discussed in groups, in order to agree on recommendations for interventions or activities that could address these problems.

See Box below for the main recommendations from the meeting.

Good health care could only be provided to the people of Zimbabwe, if all health workers at every level, used their knowledge and their skills optimally and in accordance with agreed standards, the meeting emphasised. Collaboration and the sharing of information at all health care levels must be the mark of the future. ❑

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Main recommendations of the meeting

Rational prescribing

- Incentives must be introduced at facility level for cost effective treatment and drug management.
- Hospital therapeutic committees should be strengthened and guidelines developed.
- Undergraduate medical (and allied) training should have a more problem-oriented approach, teaching the students skills rather than just knowledge.
- Therapeutic training must be based on the principles of rational drug use and EDLIZ. The teachers must set a good example and be seen to use EDLIZ.
- A diagnosis should be indicated on every prescription or patient card to facilitate assessment of rational use of drugs. Auditing prescribing habits and drug consumption should be promoted at all levels.
- Studies to obtain information on rational drug use must be encouraged.

Promoting EDLIZ

- Availability of EDLIZ must be assured for all health professionals.
- All medical clinical/bedside training should refer to EDLIZ, and be examinable.
- The curricula for all health workers should be revised to include training in the essential drugs concept and use of EDLIZ, and should also include teaching the principles of rational prescribing.
- Introduction course on EDLIZ and rational prescribing in Zimbabwe to be established for health professionals trained outside Zimbabwe.

Drug availability

- Privatisation of the Government Medical Stores.
- Improve dissemination of information regarding drug consumption and unavailability.
- Promote computerisation of Medical Stores and central/provincial hospitals.
- Promote supervision in drug management.

Photo: B. Trap

A clinic in rural Zimbabwe. The country's campaign to promote the rational use of drugs now targets prescribers at all levels of health care

RATIONAL USE

Effective drug management: Thai course spreads the message

Paul Spivey*

EDM-19 announced that the Aberdeen course in "Effective Drug Management and Rational Drug Use" (EDMRDU) would spread its wings. The "flight" took 11 hours in an easterly direction to Khon Kaen in Thailand. The purpose was to see if the course could be given effectively in a regional location, which would make it available to a greater number of participants from that region.

Khon Kaen, one of Thailand's major cities, is about one hour's flight North-East from the capital, Bangkok. The University is spread over a large and green campus with many trees and open areas. The Faculty of Pharmaceutical Sciences extends into a building which houses the Faculty of Medicine and the Teaching Hospital (Srinagarind Hospital). It was here that the EDMRDU course was conducted for five weeks in November and December 1995, at the invitation of the Thai Consortium of Pharmacy Faculties, in collaboration with WHO's Action Programme on Essential Drugs and the Robert Gordon University, Aberdeen, Scotland.

At an opening ceremony, the President of Khon Kaen University extended a warm welcome to the 10 participants who represented seven different countries – Bhutan, Cambodia, Maldives, Palau, The Lao People's Democratic Republic, Solomon Islands and Thailand. Three of the participants worked in hospital pharmacy, two in central medical stores, four in country drug programme management and development, and one in pharmacy education.

The basis of the course was the core material from the Aberdeen curriculum. The material deals with national drug policy, drug supply management issues (selection, quantification, procurement, and storage and distribution), rational use of drugs (formularies, information, standard treatment guidelines, drug use research), management of resources (financial and human), quality assurance, teaching and communication. Overseas visiting lecturers complemented the contribution of lecturers from Thailand.

The style of the course also followed that used in Aberdeen. This encourages participants to highlight, analyse and discuss problem areas and possible solutions relating to their personal and national working situations. There was plenty of active involvement (and laughter!). One participant wrote, "the contributions of my colleagues also helped me a lot... the different systems and background... means more when they are put together to be discussed".

Back in Scotland...

The next annual course in Aberdeen will be held from 12 May to 11 July 1997. It will look at vital aspects of drug management and rational drug use at national and institutional or programme levels. The majority of lecturers have experience of working in Africa or Asia. The course is suitable for health professionals, especially pharmacists, who are involved in the management of drug supply, whether in the public sector or in nongovernmental organizations. Tuition fees are £2,800. ❑

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Photo: P. Spivey

The course encouraged student involvement, as here during a session on stock control

India: guidelines on rational use in medical curricula

FURTHER progress has been made in India's drive to ensure that instruction in rational prescribing takes its rightful place in medical training. A three-day national level consultation has resulted in the formation of a task force of experts to develop guidelines for undergraduate and intern training in rational drug use. The point was forcefully made that the credibility of such training would grow with the increase in the number of medical schools involved in training in rational use of drugs. Organized by the Foundation for Health Action, the Calcutta School of Tropical Medicine and the West Bengal Voluntary Health Association, the meeting took place in Calcutta from 2–4 November 1995. It brought together 25 senior professors and heads of department from medical colleges, representatives of professional bodies, and consumers. Participants discussed how to make young medical graduates aware of the consequences of irrational drug use and the importance of making special provision for training in rational drug use in undergraduate curricula. ❑

Philippines: monitoring drug prices

As part of the Philippines National Drug Policy, there is a commitment to monitoring drug prices and keeping consumers well informed on this subject. All drugs on the market are available under generic names but may also be sold under different brand names. Prices for similar drugs with different brand names can vary considerably. However, they are generally comparable in terms of safety and efficacy. The example of rifampicin shows how great price differentials can be (see Box).

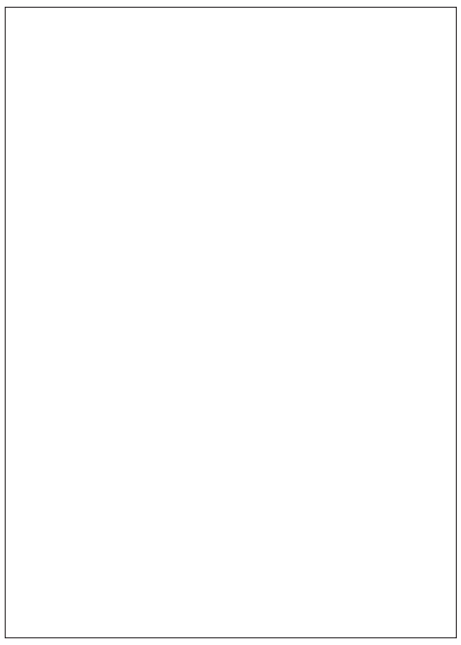
The figures give average drug prices at several drug outlets being monitored. They illustrate the savings possible if consumers exercise their right of informed choice when buying drugs. ❑

Source: RDU Update 1995: vol 4; no.2. Published by the Philippine National Drug Policy Office, c/o The National Drug Information Centre, Department of Pharmacology, College of Medicine, University of the Philippines, 547 Pedro Gil Street, Manila, the Philippines. Further information on the Philippine's drug pricing strategy may be obtained by writing to this address.

RIFAMPICIN
450 mg capsule or tablet

	Price in pesos
Medifam	20.38
Ramicin	20.37
Rimactane	22.94
Rifadine	24.17
Rifampicin (UL)	14.79
Rifampicin (USA)	15.70
Rifampicin (DLI)	8.90
Rifampicin (Lumar)	17.45
Rifampicin (Pharex)	15.26
Rifampicin (Biosis)	9.50
Highest price:	
Rifadine	24.17
Lowest price:	
Rifampicin (DLI)	8.90
Difference:	15.27
Savings/course (1 cap./day for 6 months treatment)	**2,748.60**

Prepared by the Essential Drugs Price Monitoring Unit, the Philippines, 28 July 1995.



Department of Health, the Philippines

One of the posters used in the campaign to ensure that consumers spend wisely on medicines

Correction

Dr Budiono Santoso has brought to our attention that the article in EDM-20, "From research to action: the Gunungkidul experience", was attributed to him instead of Dr Sunartono and Drs Darminto. Dr Sunartono is Former Head of Gunungkidul District Health Office, and now Head of Sleman District Health Office, Jalan Candi Jonggrang, Sleman DIY, Indonesia. Drs Darminto is Head of Gunungkidul District Pharmaceutical Warehouse, Gunungkidul District Health Office, Jalan Kolonel Sugiyono No. 1, Wonosari, Gunungkidul, DIY, Indonesia. We apologise for the error.

RATIONAL USE

Maldives: workshop boosts collaboration

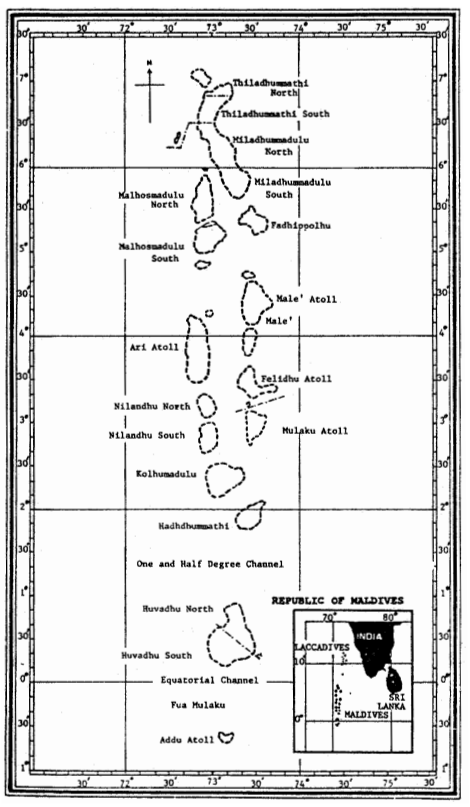
In spite of a delayed start due to bad weather, nothing could dampen the enthusiasm of participants at a workshop for health professionals held in Seenu, Hithadhoo, the Maldives, from 15–17 August 1995. Organized by the Maldives Essential Drugs Programme, the workshop aimed to improve rational drug use, drug supply management, and diagnostic and communication skills. Thirty doctors, dentists, pharmacists, pharmacy assistants and community health workers from the southern atolls of Gaaf Alif, Gaaf Dhaal, Fuvahmulah and Seenu, benefited from sharing experiences and exchanging views.

Discussions centred on the essential drugs concept and its implementation through the Essential Drugs Programme. A session on clinical diagnosis and treatment focused on how to diagnose more accurately and how to treat the underlying cause of illness economically. Case studies were used to help participants identify and solve their common prescribing problems. Participants' justifications for first-line drug choices were analysed on the grounds of pharmacology, epidemiology and sociocultural beliefs. In addition to prescribing behaviour, self-medication, and patient information and adherence to treatment were discussed.

The strengths and weaknesses of the current drug supply system were reviewed. Discussions ranged from methods of record keeping and inventory control, and regulations on drug import and sale, to how to protect drugs from high temperatures, humidity, sunlight and pests. Participants also reviewed the various forms of financing drug supplies. The Government wants to encourage those capable of paying for treatment to do so. However, the workshop stressed the importance of developing criteria to help health professionals identify the needy, who should receive drugs free of charge.

One reason for the workshop's success was the open-minded, cross disciplinary approach to issues encouraged by the facilitators. They helped participants apply critical, logical thought rather than simply using standard techniques and guidelines. Various teaching methods were used, including small group discussions, "buzz" sessions and demonstrations. ❑

Report prepared by Oliver M. Hazemba, former UN Volunteer Pharmacist in the Maldives and Aishath Ibrahim Didi, Pharmaceuticals Coordinator, Ministry of Health and Welfare, Male, Maldives.



The Republic of Maldives is made up of hundreds of islands grouped into atolls, which stretch for hundreds of miles in the Indian Ocean – a problem for those supplying drugs, and one of the issues addressed at the workshop

SUPPLY

New guidelines for drug donations

In recent years the various agencies involved in humanitarian relief efforts have been called on to respond to an increasing number of large-scale emergencies and disasters. Many of these pose a serious threat to health and much of the assistance provided is in the form of drugs, which can play a vital role in reducing morbidity and mortality in such situations. In their determination to ensure that every drug donated is safe, effective and needed, WHO and other agencies involved in international relief work have produced important new guidelines, which are reproduced here in full.*

Health Action International

Donations must be appropriate

Introduction

These Guidelines for Drug Donations have been developed by the World Health Organization (WHO) and reflect a consensus between the major international agencies active in humanitarian emergency relief (World Health Organization, Office of the United Nations High Commissioner for Refugees, United Nations Children's Fund, International Committee of the Red Cross, International Federation of the Red Cross and Red Crescent Societies, Médecins sans Frontières, Churches' Action for Health of the World Council of Churches and OXFAM). In several rounds of consultation, comments by over 100 humanitarian organizations and individual experts were taken into consideration.

The guidelines aim to improve the quality of drug donations, not to hinder them. They are not an international regulation, but intended to serve as a basis for national or institutional guidelines, to be reviewed, adapted and implemented by governments and organizations dealing with drug donations. They are issued as an interagency document and will be reviewed after one year on the basis of comments received during their use.

There are many different scenarios for drug donations. They may take place in acute emergencies or as part of development aid in non emergency situations. They may be corporate donations (direct or through private voluntary organizations), aid by governments or donations aimed directly at single health facilities. And although there are legitimate differences between these scenarios, there are many basic rules for an appropriate donation that apply to all. The guidelines aim to describe this common core of "Good Donation Practice".

This document starts with a discussion on the need for guidelines, followed by a presentation of the four core principles for drug donations. The guidelines for drug donations are presented in Chapter III. When necessary for specific situations, possible exceptions to the general guidelines are indicated. Chapter IV presents some suggestions on other ways that donors may help, and Chapter V contains practical advice on how to implement a policy on drug donations.

I The need for guidelines

In the face of disaster and suffering there is a natural human impulse to reach out and help those in need. Medicines are an essential element in alleviating suffering, and international humanitarian relief efforts can greatly benefit from donations of appropriate drugs.

Unfortunately, there are also many examples of drug donations which cause problems instead of being helpful. A sizable disaster does not always lead to an objective assessment of emergency medical needs based on epidemiological data and past experience. Very often an emotional appeal for massive medical assistance is issued without guidance on what are the priority needs. Numerous examples of inappropriate drug donations have been reported (see Boxes). The main problems can be summarised as follows:

- Donated drugs are often not relevant for the emergency situation, for the disease pattern or for the level of care that is available. They are often unknown by local health professionals and patients, and may not comply with locally agreed drug policies and

standard treatment guidelines; they may even be dangerous.

- Many donated drugs arrive unsorted and labelled in a language which is not easily understood. Some donated drugs come under trade names which are not registered for use in the recipient country, and without an International Nonproprietary Name (INN, or generic name) on the label.
- The quality of the drugs does not always comply with standards in the donor country. For example, donated drugs may have expired before they reach the patient, or they may be drugs or free samples returned to pharmacies by patients or health professionals.
- The donor agency sometimes ignores local administrative procedures for receiving and distributing medical supplies. The distribution plan of the donor agencies may conflict with the wishes of national authorities.
- Donated drugs may have a high declared value, e.g. the market value in the donor country rather than the world market price. In such cases import taxes and overheads for storage and distribution may be unnecessarily high, and the (inflated) value of the donation may be deducted from the government drug budget.
- Drugs may be donated in the wrong quantities, and some stocks may have to be destroyed. This is wasteful and creates problems of disposal at the receiving end.

Armenia, 1988

After the earthquake, 5,000 tons of drugs and medical supplies worth US$55 million were sent. This quantity far exceeded needs. It took 50 people six months to gain a clear picture of the drugs that had been received. Eight percent of the drugs had expired on arrival, and 4% were destroyed by frost. Of the remaining 88%, only 30% were easy to identify and only 42% were relevant for an emergency situation. The majority of the drugs were only labelled with brand names[1].

There are several underlying reasons for these problems. Probably the most important factor is the common but mistaken belief that in an acute emergency any type of drug is better than none at all. Another important factor is a general lack of communication between the donor and the recipient, leading to many unnecessary donations. This is unfortunate because in disaster situations and war zones inappropriate drug donations create an extra workload in sorting, storage and distribution, and can easily overstretch the capacity of precious human resources and scarce transport volume. Often, the total handling costs (duties, storage, transport) are higher than the value of the drugs. Stockpiling of unused drugs can encourage pilfering and black market sales.

Donating returned drugs (unused drugs returned to a pharmacy for safe disposal, or free samples given to health professionals) is an example of double standards, because in most countries their use would not be permitted due to quality control regulations. Apart from quality aspects, such donations also frustrate management efforts to administer drug stocks in a rational way. Prescribers are confronted with many different drugs and brands in ever changing dosages; patients on long-term treatment suffer because the same drug may not be available the next time. For these reasons this type of donation is forbidden in an increasing number of countries and is generally discouraged.

In the early 1980s the first guidelines for drug donations were developed by international humanitarian organizations, such as the International Committee of the Red Cross (ICRC) and the Christian Medical Commission (CMC) of the World Council of Churches, later called Churches' Action for Health[2]. In 1990 the WHO Action Programme on Essential Drugs, in close collaboration with the major international emergency aid agencies, issued a first set of WHO guidelines for donors[3], later refined by the WHO Expert Committee on the Use of Essential Drugs[4]. In 1994 the WHO office in Zagreb issued specific guidelines for humanitarian assistance to former Yugoslavia[5].

Eritrea, 1989

During the war for independence, despite careful wording of appeals, many inappropriate donations were received. Examples were: seven truck loads of expired aspirin tablets that took six months to burn; a whole container of unsolicited cardiovascular drugs with two months to expiry; and 30,000 half-litre bottles of expired amino-acid infusion that could not be disposed of anywhere near a settlement because of the smell[6].

In view of the existence of these different drug donation guidelines, the need was felt for one comprehensive set of guidelines that would be endorsed and used by all major international agencies active in emergency relief. For this reason a first draft was prepared by the WHO Action Programme on Essential Drugs and further refined in close collaboration with the division of Drug Management and Policies and the division of Emergency Preparedness, major international relief organizations and a large number of international experts. The final text represents the consensus between the World Health Organization, UNICEF, the Office of the United Nations High Commissioner for Refugees, the International Committee of the Red Cross, the International Federation of Red Cross and Red Crescent Societies, Churches' Action for Health of the World Council of Churches, Médecins sans Frontières and OXFAM. In the process, comments by over 100 humanitarian organizations and individual experts were taken into consideration.

Sudan, 1990

A large consignment of drugs was sent to war-devastated southern Sudan. Each box contained a collection of small packets of drugs, some partly used. All were labelled in French, a language not spoken in Sudan. Most drugs were inappropriate, some could be dangerous. These included: contact lens solution, appetite stimulants, mono-amine oxidase inhibitors (dangerous in Sudan), X-ray solutions, drugs against hypercholesterolaemia, and expired antibiotics. Of 50 boxes, 12 contained drugs of some use[7].

The examples of inappropriate donations quoted above constitute ample reasons to develop international guidelines for drug donations. In summary, guidelines are needed because:

- Donors intend well, but often do not realise the possible inconveniences and unwanted consequences at the receiving end.
- Donor and recipient do not communicate on equal terms. Recipients may need support in specifying how they want to be helped.
- Drugs do not arrive in a vacuum. Drug needs may vary between countries and from situation to situation. Drug donations must be based on a sound analysis of the needs, and their selection and distribution must fit within existing drug policies and administrative systems. Unsolicited and unnecessary drug donations are wasteful and should not occur.
- The quality requirements of drugs are different from other donated items, such as food and clothing. Drugs can be harmful if misused, they need to be identified easily through labels and written information, they may expire, and they may have to be destroyed in a professional way.

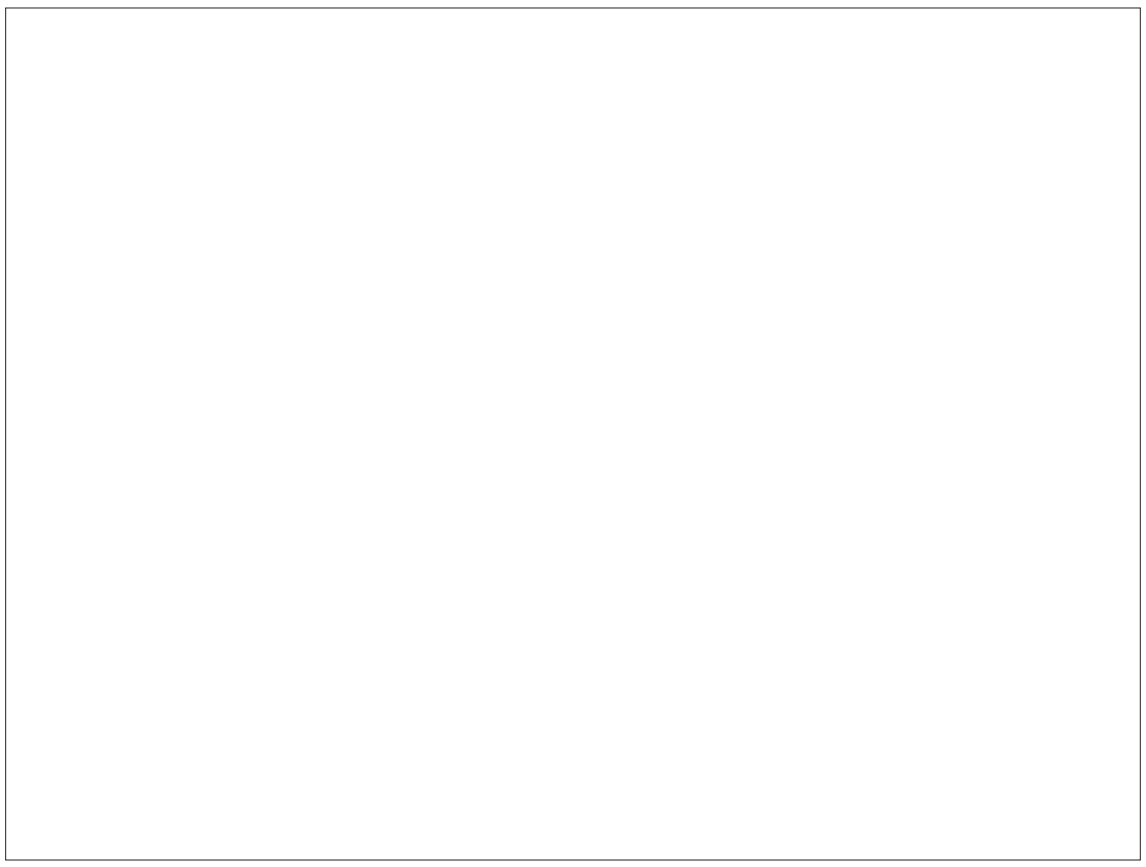


Photo: WHO/MSF Belgium

In emergency situations, such as the 1985 Mexican earthquake, drugs and other medical supplies are the first and most crucial needs of the victims

France, 1991

Pharmaciens sans Frontières collected 4 million kg of unused drugs from 4,000 pharmacies in France. These were sorted out in 88 centres in the country. Only about 20% could be used for international aid programmes, and 80% were burnt[8].

II Core principles

The 12 articles of the Guidelines for Drug Donations are based on four core principles. The first and paramount principle is that a drug donation should benefit the recipient to the maximum extent possible. This implies that all donations should be based on an expressed need and that unsolicited drug donations are to be discouraged. The second principle is that a donation should be given with full respect for the wishes and authority of the recipient, and be supportive of existing government health policies and administrative arrangements. The third principle is that there should be no double standards in quality: if the quality of an item is unacceptable in the donor country, it is also unacceptable as a donation. The fourth principle is that there should be effective communication between the donor and the recipient: donations should be based on an expressed need and should not be sent unannounced.

Core principles of a donation

1. Maximum benefit to the recipient
2. Respect for wishes and authority of the recipient
3. No double standards in quality
4. Effective communication between donor and recipient

cont'd on pg. 8

III Guidelines for drug donations

Selection of drugs

1 All drug donations should be based on an expressed need and be relevant to the disease pattern in the recipient country. Drugs should not be sent without prior consent by the recipient.

Justification and explanation
This provision stresses the point that it is the prime responsibility of the recipients to specify their needs. It is intended to prevent unsolicited donations, and donations which arrive unannounced and unwanted. It also empowers the recipients to refuse unwanted gifts.

Possible exceptions
In acute emergencies the need for prior consent by the recipient may be waived, provided the drugs are amongst those on the WHO Model List of Essential Drugs[9] that are included in the UN list of emergency relief items recommended for use in acute emergencies[10].

2 All donated drugs or their generic equivalents should be approved for use in the recipient country and appear on the national list of essential drugs, or, if a national list is not available, on the WHO Model List of Essential Drugs, unless specifically requested otherwise by the recipient.

Justification and explanation
This provision is intended to ensure that drug donations comply with national drug policies and essential drugs programmes. It aims at maximising the positive impact of the donation, and prevents the donation of drugs which are unnecessary and/or unknown in the recipient country.

Possible exceptions
An exception can be made for drugs needed in sudden outbreaks of uncommon or newly emerging diseases, since such drugs may not be approved for use in the recipient country.

3 The presentation, strength and formulation of donated drugs should, as much as possible, be similar to those commonly used in the recipient country.

Justification and explanation
Most staff working at different health care levels in the recipient country have been trained to use a certain formulation and dosage schedule and cannot constantly change their treatment practices. Moreover, they often have insufficient training in performing the necessary dosage calculations required for such changes.

Quality assurance and shelf-life

4 All donated drugs should be obtained from a reliable source and comply with quality standards in both the donor and recipient country. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce[11] should be used.

Justification and explanation
This provision prevents double standards: drugs of unacceptable quality in the donor country should not be donated to other countries. Donated drugs should be authorised for sale in the country of origin, and manufactured in accordance with international standards of Good Manufacturing Practice (GMP).

Possible exceptions
In acute emergencies the use of the WHO Certification Scheme may not be practical. However, if it is not used, a justification should be given by the donor. When donors provide funds to purchase drugs from local producers, those which comply with national standards should not be excluded on the sole grounds that they do not meet quality standards of the donor country.

5 No drugs should be donated that have been issued to patients and then returned to a pharmacy or elsewhere, or were given to health professionals as free samples.

Justification and explanation
Patients return unused drugs to a pharmacy to ensure their safe disposal; the same applies to drug samples that have been received by health workers. In most countries it is not allowed to issue such drugs to other patients, because their quality cannot be guaranteed. For this reason returned drugs should not be donated either. In addition to quality issues, returned drugs are very difficult to manage at the receiving end because of broken packages and small quantities involved.

6 After arrival in the recipient country all donated drugs should have a remaining shelf-life of at least one year.

Justification and explanation
In many recipient countries, and especially under emergency situations, there are logistical problems. Very often the regular drug distribution system has limited possibilities for immediate distribution. Regular distribution through different storage levels (e.g. central store, provincial store, district hospital) may take six to nine months. This provision especially prevents the donation of drugs just before their expiry as in most cases such drugs would only reach the patient after expiry.

Possible exceptions
An exception should be made for drugs with a total shelf-life of less than two years, in which case at least one-third of the shelf-life should remain. An exception can also be made for direct donations to specific health centres in the recipient country, provided the responsible professional at the receiving end is aware of the shelf-life and the remaining shelf-life allows for proper administration prior to expiration. In all cases it is important that the date of arrival be communicated to the recipient well in advance.

Presentation, packing and labelling

7 All drugs should be labelled in a language that is easily understood by health professionals in the recipient country; the label on each individual container should at least contain the International Nonproprietary Name (INN, or generic name), batch number, dosage form, strength, name of manufacturer, quantity in the container, storage conditions and expiry date.

Justification and explanation
All donated drugs, including those under brand name, should be labelled also with their INN or the official generic name. Most training programmes are based on the use of generic names. Receiving drugs under different and often unknown brand names and without the INN is confusing for health workers and can even be dangerous for patients. In case of injections, the route of administration should be indicated.

8 As much as possible, donated drugs should be presented in larger quantity units and hospital packs.

Justification and explanation
Large quantity packs are cheaper, less bulky to transport and conform better with public sector supply systems in most developing countries. This provision also prevents the donation of drugs in sample packages, which are impractical to manage. In precarious situations, the donations of paediatric syrups and mixtures may be inappropriate because of logistical problems and their potential misuse.

9 All drug donations should be packed in accordance with international shipping regulations, and be accompanied by a detailed packing list which specifies the contents of each numbered carton by INN, dosage form, quantity, batch number, expiry date, volume, weight and any special storage conditions. The weight per carton should not exceed 50 kilograms. Drugs should not be mixed with other supplies in the same carton.

Justification and explanation
This provision is intended to facilitate the administration, storage and distribution of donations in emergency situations, as the identification and management of unmarked boxes with mixed drugs is very time and labour intensive. This provision specifically discourages donations of small quantities of mixed drugs. The maximum weight of 50 kg ensures that each carton can be handled without special equipment.

Information and management

10 Recipients should be informed of all drug donations that are being considered, prepared or actually underway.

Justification and explanation
Many drug donations arrive unannounced. Detailed advance information on all drug donations is essential to enable the recipient to plan for the receipt of the donation and to coordinate the donation with other sources of supply. The information should at least include: the type and quantities of donated drugs including their International Nonproprietary Name (INN, or generic name), strength, dosage form, manufacturer and expiry date; reference to earlier correspondence (for example, the letter of consent by the recipient); the expected date of arrival and port of entry; and the identity and contact address of the donor.

11 In the recipient country the declared value of a drug donation should be based upon the wholesale price of its generic equivalent in the recipient country, or, if such information is not available, on the wholesale world-market price for its generic equivalent.

Justification and explanation
This provision is needed in the recipient country to prevent drug donations being priced according to the retail price of the product in the donor country, which may lead to elevated overhead cost for import tax, port clearance, and handling in the recipient country. It may also result in a corresponding decrease in the public sector drug budget in the recipient country.

Possible exceptions
In case of patented drugs (for which there is no generic equivalent) the wholesale price of the nearest therapeutic equivalent could be taken as a reference.

12 Costs of international and local transport, warehousing, port clearance and appropriate storage and handling should be paid by the donor agency, unless specifically agreed otherwise with the recipient in advance.

Justification and explanation
This provision prevents the recipient from being forced to spend effort and money on the clearance and transport of unannounced consignments of unwanted items, and also enables the recipient to review the list of donated items at an early stage.

IV Other ways donors can help

The New Emergency Health Kit

In the acute phase of an emergency, or in the case of displacements of refugee populations without any medical care, it is better to send a standardised kit of drugs and medical supplies that is specifically designed for this purpose. For example, the New Emergency Health Kit[3], which has been widely used since 1990, contains drugs, disposable supplies and basic equipment needed for general medical care for a population of 10,000 for three months. Its contents are based on a consensus among the same group of major international aid agencies that also issued the drug donation guidelines. It is permanently stocked by several major international suppliers (for example, UNICEF and IDA) and can be available within 48 hours. It is especially relevant in the absence of specific requests.

Donations in cash

After the acute phase of the emergency is over, a donation in cash for local or regional purchase of essential drugs is usually much more welcome than further drug donations in kind. Such a cash contribution is very supportive to the activities of the local government or coordinating committee, it is supportive to the local and regional pharmaceutical industry and it may also be more cost effective. In addition, prescribers and patients are usually more familiar with locally produced drugs.

> ***Russian Federation, 1992***
>
> Russian pharmaceutical production has fallen far below its 1990 level, and donations of drugs have been welcomed. However, initial enthusiasm soured when the nature of some donations was discovered. Examples of donations include: 189,000 bottles of dextromethorfan cough syrup; pentoxifylline and clonidine as the only antihypertensive items; triamterene and spironolactone as diuretics; pancreatic enzyme and bismuth preparations as the only gastrointestinal drugs[12].

Additional guidelines for drug donations as part of development aid

When drug donations are given between governments as humanitarian support to longlasting complex emergencies and as regular development (commodity) aid, there is usually more time to consider specific demands from the side of the recipient. On the other hand, there is also time to link more restrictions to the donation, e.g. to products from manufacturers in the donor country, and to drugs registered for use in the recipient country.

It should be recognised that drugs do not arrive in an administrative vacuum. Drug donations should not create an abnormal situation which may obstruct or delay national capacity building in selection, procurement, storage, distribution and rational use of drugs. Special care should therefore be taken that the donated drugs respond to an expressed need, comply with the national drug policy, and are in accordance with national treatment guidelines in the recipient country. Administratively, the drugs should be treated as if they were procured. This means that they should be registered or authorised for use in the country through the same procedure that is used for government tenders. They should be entered into the inventory, distributed through the existing distribution channels and be subject to the same quality assurance procedures. If cost-sharing procedures are operational in the recipient country, the donated drugs should not automatically be distributed free of charge.

> ***Guinea Bissau, 1993***
>
> In September 1993 eight tons of donated drugs were sent; all were collected from pharmacies in quantities between one and 100 tablets. The donation contained 22,123 packages of 1,714 different drugs which were very difficult to manage and greatly interfered with government efforts to rationalise drug supply and drug use[13].

V How to implement a policy on drug donations

Management of drug donations by the recipient

Define national guidelines for drug donations

It is difficult for a recipient to refuse a donation that has already arrived. Prevention is therefore better than cure. Recipients should indicate to their prospective donors what kind of assistance they need and how they would like to receive it. If this information is provided in a rational and professional way, most donors will appreciate it and will comply.

Therefore, recipients should first formulate their own national guidelines for drug donations, on the basis of these international guidelines. They can also be included in the national drug policy. These national guidelines should then be officially presented and explained to the donor community. Only after they have been presented and officially published can they be enforced.

Define administrative procedures for receiving drug donations

It is not enough for the recipient to adopt and publish the general guidelines on the selection, quality, presentation and management of drug donations. Administrative procedures need to be developed by the recipient to maximise the potential benefit of drug donations. As much as possible such arrangements should be linked with existing drug supply systems, but there are several questions which apply to donations only. Examples of such important questions, which have to be addressed in each country, are:

- Who is responsible for defining the needs, and who will prioritise them?
- Who coordinates all drug donations?
- Which documents are needed when a donation is planned; who should receive them?
- Which procedure is used when donations do not follow the guidelines?
- What are the criteria for accepting/rejecting a donation; who makes the final decision?
- Who coordinates reception, storage and distribution of the donated drugs?
- How are donations valued and entered into the budget/expenditure records?
- How will inappropriate donations be disposed of?

Specify the needs for donated drugs

The third important action by the recipient is to specify the needs for donated drugs as much as possible. This puts the onus on the recipient to carefully prepare such requests, indicating the required quantities and prioritising the items. The more information given, the better. Information on donations that are already in the pipeline, or anticipated, is very helpful to other potential donors. Full information from the side of the recipient is greatly appreciated by donors and pays off in the long run.

> ***Lithuania, 1993***
>
> Eleven women in Lithuania temporarily lost their eyesight after using a donated drug. The drug, closantel, was a veterinary anthelmintic but was mistakenly given to treat endometritis. The drug had been received without product information or package insert, and doctors had tried to identify the product by matching its name with those on leaflets of other products[14].

Manage donated drugs carefully

The value of donated drugs can be considerable, and the gift should be treated with due care. On arrival the drugs should be inspected and their receipt confirmed to the donor agency. They should then be stored and distributed in accordance with normal principles of good pharmacy practice and under the responsibility of adequately trained professionals. There must be due vigilance to ensure that donated products are not diverted for export, commercial sale, or into illicit channels.

Action required from donor agencies

Donors should always respect the four core principles for drug donations presented above. Donors should also respect the national guidelines for drug donations and respond to the priority needs indicated by the recipient. Unsolicited donations should be prevented as much as possible.

> ***Former Yugoslavia, 1994, 1995***
>
> Of all drug donations received by the WHO field office in Zagreb in 1994, 15% were completely unusable and 30% were not needed[15]. By the end of 1995, 340 tons of expired drugs were stored in Mostar. Most of these were donated by different European nations[16].

The public at large in the donor country is not always aware of the common problems with drug donations. It is therefore important that governments in donor countries spend some effort to create more public awareness on "good donor practice". The best moment for this is probably at the time of the public appeal through the media.

Within the recipient country it is recommended that the different donors choose a "lead-donor" amongst themselves, who coordinates donor activities and who may also act as the central contact point in discussions with the recipient government.

The recipient country should supply as much information as possible on requested and approved donations. On the other hand, the donors themselves should also inform the recipient well in advance and in great detail about which donations are coming, and when. This will greatly assist the coordinating body in the recipient country to plan for the proper reception of the donations, and to identify the need for additional supplies. ❑

*Copies of **Guidelines for Drug Donations**, WHO/DAP/96.2, are available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.*

** The guidelines may be reproduced and translated, in part or in whole, but not for sale nor for use in conjunction with commercial purposes.*

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A handy hint: the core guidelines on page 8 can be photocopied easily if turned sideways to make two A4 pages.

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SUPPLY

Drug management in the Government Sector: the Tamil Nadu Model

R. Poornalingam*

Improvements in drug procurement and distribution systems can lead not only to increased efficiency, quality and availability of drugs but also to considerable financial savings. It is therefore natural that health ministries throughout the world are considering how they can effect such improvements. Here we describe how one Indian State, Tamil Nadu, has tackled the issue and is beginning to reap the benefits from the changes it has introduced.

TAMIL NADU is one of India's largest, more urbanised States, with a relatively well developed infrastructure. The last census, in 1991, showed a population of 55.9 million, with approximately 34% living in urban areas. The State has a good industrial base and there are a number of drug manufacturing companies. There has always been a plentiful supply of drugs available in the private sector. However, the poorer sections of the population cannot afford these drugs and use the Government sector, which dispenses drugs free of charge. But drug availability in the public health system was a problem. The State Government of Tamil Nadu decided to act, and this article describes the measures it has taken to ensure that all its people have access to essential drugs.

Considering the options

The State Government's main objective was to purchase quality drugs at competitive prices and make essential drugs available to all Government health facilities. Inefficient indenting procedures and poor inventory management were seen as major problems. Faced with a number of options, the Government decided the best for Tamil Nadu was an open tender system. It would no longer permit any purchase or price preference to particular suppliers. The Government's concern with open tendering was how to ensure drug quality. It decided to purchase drugs only from manufacturers and not, as previously, through agents. It was further stipulated that these manufacturers should have a Good Manufacturing Practice Certificate and a market standing of at least three years. A minimum turnover was also fixed, to eliminate very small firms which it was thought might be unable to keep up delivery schedules. The Government clearly spelt out its stipulations, to try to ensure that only reputable firms would tender. To avoid dependence on one firm, it was decided to use a number of suppliers willing to match the lowest price. For its part, a Government decision to pay for drugs within 15 days encouraged manufacturers to quote competitive rates.

Change has also been introduced in the area of drug packaging. To prevent wastage and pilfering, manufacturers use strip or blister packing for all tablets, instead of the previous system of hand packing in bulk at the time of distribution. The strips and tablets are marked to show that the drugs are manufactured only for State Government supply and not for sale. Concern was expressed that strip packing could increase drug costs. However, the counter argument, that any marginal increases would be more than offset by reduced wastage and increased public acceptance of the drugs, won the day.

Creating Tamil Nadu Medical Services Corporation

A major Government initiative was to set up Tamil Nadu Medical Services Corporation (TNMSC), a Government company, to provide necessary services to Government hospitals. One of the main objectives of the Corporation is to organize an efficient, centralised drug procurement and distribution system. The Corporation has a Board of Directors, with the State's Secretary for Health as an ex-officio Chairman, and a full-time Managing Director.

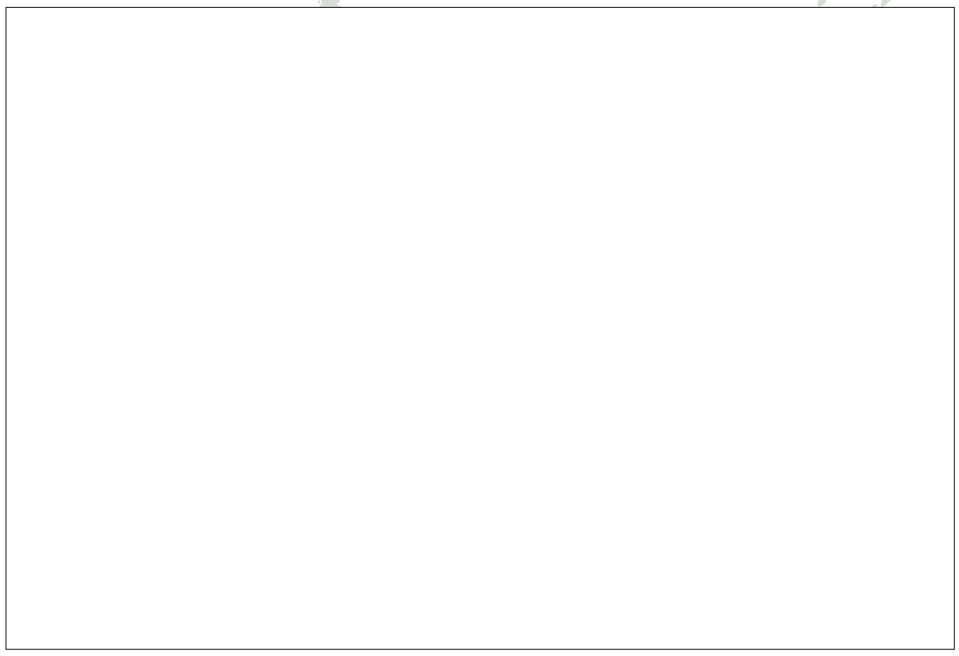

Photo: R. Poornalingam

A selection of the drugs stocked by a typical godown in Tamil Nadu

Promoting the essential drugs concept

Under the previous system, hospitals put in requisitions for drugs and then tenders were invited. It was soon evident that the total of 960 drugs procured in this way could be substantially reduced. Many of the drugs were wanted in very small quantities, and central purchasing for such small quantities was uneconomical. Other drugs on the list were deemed non essential. The Corporation decided to introduce the essential drugs concept and an essential drugs list based on WHO's Model List.

TNMSC's first task was to finalise the list of essential drugs it would procure. A Committee of leading professors of medicine and therapeutics (including a WHO representative) was constituted to do this. The Committee held several meetings with drug managers and specialists, and after detailed discussions a final list of 240 generic drugs was agreed. An analysis of these drugs indicated that only about 100 drugs made up 90% of the total value of all 240 drugs. While recognising the scope for further reduction in the list, it was decided not to introduce more cuts in its first year. As services in primary health centres and sub-centres are limited, the Committee decided to standardise the drugs that can be supplied to them. The centres can only requisition drugs outside this list in special circumstances.

The reduction in the existing drugs list meant that the Corporation could procure the drugs it needed with approximately 90% of its drug budget. This left other drugs to be purchased locally by the hospitals out of the remaining 10%, which TNMSC divided among them. These funds cannot be used to purchase drugs which are on the Corporation's list. After further discussions, the list of drugs which can be procured locally was finalised and circulated to all hospitals. To minimise costs, the possibility of calling for tenders for such drugs was considered. But this would have reduced flexibility, been time consuming and in emergencies hospitals might not have received drugs quickly enough.

In a centralised purchase and distribution system, such as that created in Tamil Nadu, some degree of flexibility for local purchase by medical institutions is essential to meet the needs of all. The system of distributing 10% of the annual budget to hospitals has helped the Corporation counter any criticism that the drugs list is inadequate.

Improving distribution

The main objective of Tamil Nadu's drug management policy is to ensure regular supply and prevent stockouts. Previously when drug companies received an order they sent supplies to the medical institution concerned. One or two companies tended to receive huge orders which they could not meet. Another problem was the considerable delay in paying companies, so that they stopped supplying. It was decided to create a chain of "godowns", warehouses which stock all drugs. A warehouse for storage and distribution of drugs has been established in each of the State's 23 districts. Drug manufacturers are required to supply the drugs to the warehouse. A distribution schedule has been given to the hospitals, which can take drugs from the store according to that schedule. The drug godowns carry three months' stock, with hospitals permitted to draw a month's supply at a time. The safety stock limit is about one month's requirement, although this depends on the turnover of the particular drug and the lead time for obtaining supplies.

Raising cost consciousness

Under the previous system hospitals kept on buying drugs without any accurate assessment of future requirements. Very quickly their funds were exhausted, leading to shortages even of essential drugs. There was no preference for low cost options, largely because there were no incentives for cost consciousness. Instead it was decided to distribute drugs to the hospitals within an overall budgetary allocation. Each institution is given a pass book, indicating its annual financial entitlement, and within this it can draw any drug from the district godown. There is no need for an advance requisition. Any drug on the approved list can be obtained, provided funds are available. It is the Corporations's responsibility to order drugs well in advance, based on turnover. To prevent institutions exhausting their funds too quickly, drug supply is controlled via the quarterly allocation. The system is simple and user friendly, in that hospitals do not have to forecast their requirements in advance. They can requisition based on actual consumption and so avoid wastage. If funds are scarce, the hospital knows the price of drugs on the approved list and can choose low cost alternatives. As part of TNMSC's proposed computerisation process, it is hoped to link each hospital's drug consumption to morbidity patterns and thus improve rational drug use.

Quality control: a high priority

TNMSC was anxious to change the quality control system, as sampling was infrequent, the sampling system unscientific and complaints about drug quality common. The Corporation decided on an in-house quality control organization, with testing contracted out to reliable companies. A highly qualified quality control manager was appointed and devised a system for drawing samples and testing drugs. Samples are picked at the godowns by the staff there and by quality control staff. The samples are coded and sent to reputable private laboratories hired by the Corporation.

Increased availability

The Government of Tamil Nadu's innovations in drug procurement and management have improved drug availability in nearly 2000 Government medical institutions throughout the State. There is better budgetary control on drug consumption and medical institutions have become more cost conscious. There has been a significant improvement in the quality and appearance of supplies in the Government sector. The planned computerisation of the entire operation should enable even better inventory management, cost control and improved availability of drugs in hospitals. ❑

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SUPPLY

PROMESS: a model supply centre for essential drugs in Haiti

Guy Rino Meyers*

MAJOR humanitarian aid programmes are set up in response to specific, urgent needs. Unfortunately, they all too often have a detrimental effect on existing health facilities. It only takes a few projects involving the distribution of free drugs to seriously undermine cost recovery within health institutions and thus threaten their very existence.

When the Pan-American Health Organization (PAHO)/WHO Regional Office for the Americas (AMRO) undertook to set up humanitarian aid programmes in Haiti, it was aware of such pitfalls and strove to avoid them. PAHO/WHO took its guiding principles of supply from the goals of the Haiti Action Programme on Essential Drugs and, in August 1992, set up PROMESS (named after the Programme de Médicaments Essentiels), now a permanent distribution facility for essential drugs and medical supplies.

Although PROMESS was founded at a time of major political upheaval, primarily to respond to the specific needs of humanitarian aid programmes, it would be the envy of many countries today. The Centre is modern and operational, forming the backbone of the Haiti Essential Drugs Programme. Since it covers the entire country, PROMESS is already promoting the rational use of essential drugs and helping reinforce the national pharmaceutical sector. In the near future, the Centre could also provide substantial support in restructuring Haiti's health network.

The Haitian crisis 1991–1994

In February 1991, as Haiti's democratically elected Government came to power, it was hoped that development would finally be possible for the poorest country in the Americas. Expectations were high, particularly for the woefully inadequate health system. Barely seven months later, hopes for change were dashed by a military coup that plunged the country into an unprecedented political crisis. The international community was quick to react: most development projects were suspended, as was, *de facto*, all cooperation between technical agencies and the Haitian authorities. The Organization of American States imposed a first trade embargo, and the United Nations soon followed suit.

The health sector was in a state of emergency, and PAHO/WHO distributed an initial batch of drugs to selected institutions in order to meet the most urgent requirements. This necessary measure quickly proved to be inadequate since, contrary to expectations, the crisis continued, increasing the likelihood of violent clashes, a cholera epidemic, a rapid deterioration in health conditions and a substantial rise in tuberculosis, AIDS and other diseases.

Supply quality: a priority of aid programmes

Such prospects led to calls for PAHO/WHO to set up major humanitarian aid programmes, one of the priorities of which would be to bolster Haiti's health network by ensuring the supply of reasonably priced, quality drugs corresponding to national needs.

It was a daunting task. Although drugs were specifically excluded from any embargo, Haitian supply networks were disrupted, and both available stocks and local production capacity were inadequate. As a result, prices rose, while at the same time purchasing power fell, due to a decline in the local economy. Before long the situation had deteriorated to such an extent that several health centres whose income was derived partially or entirely from drug distribution were in danger of going under. In addition, a number of programmes, such as those on infectious disease control, maternal and child health protection and the management of medical and surgical emergencies, relied on the availability of drugs and primary medical equipment. Without adequate supplies, the whole health sector would have been crippled.

Thus, setting up a distribution facility had already become a matter of urgency within a few short months of the coup and, in January 1992, PAHO/WHO asked donor countries to accept the principle of a supply centre adapted to the specific requirements of humanitarian aid programmes.

PROMESS: providing structure in a problem sector

At the outset, those familiar with the state of the pharmaceutical sector found PAHO/WHO's project to be highly ambitious. Even before the military coup, the sector had been experiencing a long series of problems similar to those besetting many developing countries. Not only were most people unable to pay for drugs, but the sector also had to deal with problems such as an inadequate legal framework, frequent stockouts, lack of quality control, parallel distribution of unauthorised drugs and poor training standards among professionals. The supply facility for community pharmacies, set up in 1981 as a result of a bilateral agreement between the United States Agency for International Development and the Ministry of Public Health and Population, had been unable to fulfil its mandate properly and had suspended activities in May 1991.

When the democratically elected Government came to power, the situation was so critical that on taking office the new Minister promised to establish an essential drugs policy for Haiti, with the technical assistance of PAHO/WHO. As part of the new drug policy a national supply centre would be set up, financed by the World Bank. PAHO/WHO based PROMESS on that project, which had been suspended after the military coup. In that way the Organization sought to combine humanitarian action with sustainable development of the Haitian health sector.

Sharing risks and responsibility

Setting up PROMESS in the summer of 1992 was generally considered to be a risky venture. The social and political

cont'd on pg. 12 ➠

PROMESS' staff: their selection and training are given high priority to maintain standards

Photo: PROMESS

PROMESS... cont'd from pg. 11

climate was still tense and some were concerned about the possibility of supplies being stolen, confiscated or misappropriated by the *de facto* authorities. In spite of these fears, the urgency of the situation meant that the Centre had to be up and running as fast as possible, and so PROMESS opened its doors less than a year after the coup.

Its task was simple yet ambitious. It was to:

- ensure a continuous supply and proper storage of the full range of selected essential drugs and medical goods;
- supervise the efficient distribution of available goods;
- supply full and accurate information to beneficiary institutions.

In short, PROMESS was to provide high quality services at a minimal cost to the country's entire non profit health sector.

The directors of PROMESS counted on the active involvement of all partners in health-related humanitarian aid programmes to ensure the success of this far-reaching venture, launched under such exceptional political circumstances. In fact, seeking the active involvement of those partners was one of PAHO/WHO's most decisive strategic choices. The Organization wanted to share risks and responsibilities in relation to project orientation, finance and implementation, with its technical and financial partners.

The Management Committee

Although PAHO/WHO assumed legal, technical and administrative responsibility for PROMESS, a Management Committee was set up at the outset with the role of planning, following-up, promoting and assessing the Centre's activities. This Committee was unusual in a number of respects, bringing together the main figures in the Haitian health sector. Its personal and institutional links ensured that PROMESS was present at grassroots level, while at the same time enjoying privileged relations with donors and with other UN agencies.

PAHO/WHO, the United Nations Children's Fund (UNICEF), major donors (Canada, France, the United States and the European Union) and certain NGOs were also brought in on the Management Committee. The NGOs included AOPS (Association des Oeuvres Privées de Santé, an organization coordinating health-related NGOs), ASPHA (Association de Santé Publique d'Haiti, which brings together Haitian public health workers), CDS (Centres pour le Développement et la Santé, representing a number of beneficiary institutions) and ICC (International Child Care, representing the interests of hospitals).

The Management Committee also drew on the expertise of the National Association of Importers and Exporters of Pharmaceutical Goods. The Association's involvement is worth mentioning, since it obviated needless conflict between PROMESS and the Haitian commercial drug distribution network. Depending on requirements, PROMESS purchased up to 5% of its supplies from Haitian producers and contracted out transport for 10% of its imported supplies to local firms. In spite of certain political risks, the private sector responded to PROMESS' invitations to tender and, in this way, contributed to its success. A relationship of trust and mutual respect was established which has lasted to the present day.

As soon as a new constitutional Government was appointed, the Ministry of Public Health and Population was also invited to join the Management Committee.

Selection Committee

The Selection Committee was drawn from members of the Management Committee. Its function was to rule on the eligibility of institutions seeking to be recognised by PROMESS and on the potential allocation of aid to those institutions; decisions were to be reached by consensus or, in some rare cases, by a simple majority vote of those members present. An appeals procedure was established.

PROMESS: partners and beneficiaries

From the very beginning, PROMESS has sought to respond to the specific needs of its various non profit partners in the Haitian health network – health institutions, specialised agencies and local or international NGOs.

Non profit health institutions: first-line partners

All non profit institutions legally recognised by the Ministry of Public Health and Population (public, private or mixed), and providing a genuine health service to the general public are entitled to apply to PROMESS. Whether or not they are selected and what type of aid they might be granted depends on their managerial skills, their reputation in the area concerned and the quality of their service. Consideration is also given to the ultimate beneficiaries, with priority being accorded to the most remote areas and to the most underprivileged inhabitants. Similarly, note is taken of the institution's involvement in community and preventive health programmes. Over the months, the number of non profit facilities supplied by PROMESS has grown steadily, to include small, remote clinics, centres run by the Ecumenical Aid Service (whose strong presence in remote, underprivileged communities is widely recognised) and health development centres (catering for thousands of people living in the capital's slums).

PAHO/WHO has always supported a policy of self-finance for pharmacies, in line with the general principles of the Haiti Action Programme on Essential Drugs. That policy was already well accepted in Haiti, a situation the Organization sought to preserve, especially by subsidising health-related humanitarian aid programmes. Thus, during the crisis, those centres which had been accredited by the Selection Committee generally received an initial free batch of drugs corresponding to approximately three months'requirements. This subsidy was to enable them to restore revolving funds (which had often been used up during the crisis) and facilitate the development of an adequate cost-recovery system. Following the initial subsidy, such institutions had free access to PROMESS but had to pay on delivery. In so far as available resources permitted, PROMESS took social and political developments and particular circumstances into account. For example, institutions unlikely to recover costs, such as psychiatric centres and homes, and orphanages, were granted long-term subsidies. Similarly, special arrangements were made for institutions experiencing specific problems or operating in remote or particularly underprivileged areas.

Local NGOs: partners with a wide variety of needs

Several NGOs play an essential role in the Haitian health network, which entitles them to procure supplies from PROMESS. Such NGOs include ICC, which is very active in tuberculosis control throughout the country, and the Haitian Red Cross, which is responsible for the national blood transfusion service.

International NGOs: cooperating to increase efficiency

During the Haitian crisis, a number of large international NGOs, such as Médecins sans Frontières and Médecins du Monde, sought to participate in humanitarian efforts to help the country's underprivileged. These organizations had not been active in Haiti until then. They therefore called on the Directors of the Action Programme and PROMESS to help them shape their involvement and target intervention areas, particularly in relation to the needs and absorption capacity of local partners. Such cooperation eliminated any loss of time and energy, and made it possible to combine international emergency aid with national priorities.

UN specialised agencies: serving the same population

From the outset, PROMESS has been responsible for immunization materials and for certain goods relating to maternal and child health, supplied by UNICEF. The Centre also distributes contraceptives and iron supplements for pregnant women, on behalf of the United Nations Population Fund.

Donors: better informed partners

PROMESS has already obtained backing from a number of governments (Canada, Denmark, the Netherlands, Norway, Switzerland and the United States) and from the European Union and the Organization of American States. Due to their direct involvement in the PROMESS Management Committee, several donors are in a position to appreciate the usefulness of Haiti's Action Programme on Essential Drugs

Photo: PROMESS

Good stock management is one of the key factors in PROMESS' success

and, as a result, have increased their contributions.

How PROMESS operates

The day-to-day running of PROMESS relies on the work of qualified staff members motivated by a few important general management principles.

Staff

The PAHO/WHO consultant pharmacist is responsible for the technical and financial administration of PROMESS; all other PROMESS staff members are local people. They include two pharmacists (Head of the Pharmacy Department and Head of Supplies), an administrative and financial director, an accountant, a cold-chain technician, an administrative secretary, an administrative assistant cum receptionist, two drivers, a packer, cleaning and security staff. The staff quota is minimal given the amount of work to be done.

In a sector where resources are scarce, PROMESS pays particular attention to selecting its staff members and providing them with ongoing training. It might be said – and hoped – that PROMESS is helping to reaffirm the importance of the pharmaceutical profession and attract new talent.

Product selection

PROMESS currently offers more than 300 products, including drugs, medical supplies, syringes, x-ray equipment and small surgical instruments. In so far as is possible, the Centre is seeking to become Haiti's sole medical supplier, offering institutions a range of goods corresponding to all their requirements. In this way, PROMESS hopes to facilitate the management of institutions and reduce costs.

The sales prices set by PROMESS correspond to the cost price plus 10% to cover operational expenses. During the crisis, the Centre offered its customers a fixed exchange rate (for a set period) to strengthen institutions in the face of major fluctuations in the national currency and help them plan expenditure.

PAHO/WHO decided to base the standard list of drugs and medical goods to be supplied by PROMESS on the WHO Model List of Essential Drugs and, in doing so, ignored certain products traditionally used in Haiti, such as cough lozenges and multi-vitamins. This decision created problems for some institution administrators who had difficulty adjusting to the change or who knew little about generic drugs. To ease the changeover, PAHO/WHO drew up and distributed flow charts and data-sheets explaining the use of the main drugs distributed by PROMESS. Those initiatives quite naturally became part of the training activities of the Action Programme on Essential Drugs.

Procurement procedures

PAHO/WHO's normal procurement procedures had not been designed to meet the needs of a centre the size of PROMESS, nor to cope with a crisis on the scale of that which struck Haiti. The necessary adjustments were complex and at times placed heavy demands on all involved. Nevertheless, most problems were adequately solved despite hitches, and the solutions found will now form the basis of the next revision of PAHO/WHO crisis procedures.

Today, PROMESS issues a number of limited invitations to tender to international and local institutions. Suppliers and manufacturers alike have to respect good manufacturing practices in order to ensure consistent quality. The particular circumstances surrounding the crisis and the subsequent transition period have meant that a large quantity of supplies are still being procured directly. However, a more regular form of management, based on standardised planning, should soon be possible.

The management system

PROMESS has based its management system on the locally developed Medicam software. Medicam allows operators to manage client and supplier files, monitor stock levels and process offers, invoices and reports by computer. The new version, Medicam II, also includes accounting software (Exacte), which provides a direct link between the pharmaceutical and finance divisions. PROMESS uses the PAHO/WHO bank account in accordance with the Organization's requirements.

Buildings and equipment

PROMESS is located in Port-au-Prince, the capital of Haiti. At its main site the Centre has roughly 2.085 m^2 of warehouse space and 230 m^2 of office space, with a further 400 m^2 of storage space for strategic reserves elsewhere in the capital.

PROMESS is equipped with modern technology, both for administration (computers) and for storage and transport (conveyor-belts, forklifts, etc.). In view of the unreliability of the public electricity supply, the Centre is serviced by two generators powerful enough to ensure that drugs and vaccines are properly preserved.

Distribution and decentralisation

Due to the unstable political climate in Haiti at the time PROMESS was set up, the Centre initially concentrated on supplying and maintaining stocks, while institutions themselves were responsible for collecting orders. In this way, PROMESS avoided the huge logistical, security and waste problems linked with setting up a delivery system.

While such a policy was undoubtedly inevitable in a crisis, it did penalise institutions operating far from the capital. As soon as it was feasible, PROMESS set about establishing a network of peripheral warehouses. Several are already operational and all will eventually form part of the decentralised health facilities promoted by the public authorities. This will involve a considerable degree of autonomy for community health units and corresponding pharmaceutical warehouses.

Photo: PROMESS

PROMESS currently offers more than 300 products

Some PROMESS achievements

During the crisis, PROMESS supplied a total of approximately 470 health institutions (public, private or mixed), covering an estimated number of 4,510,000 people. Institutions supplied included the country's main hospitals, clinics, health centres (with or without beds), orphanages, and psychiatric homes. Coverage (beneficiary health centres/registered health centres) varied from 45.4% in the North-East Department to 91.6% in the Department of Grand'Anse.

Within the framework of humanitarian aid programmes, donor countries invested roughly US$450,000 in setting up PROMESS (building leases, installation of cold rooms and generators, purchase of storage and distribution systems), while PAHO/WHO provided substantial technical, logistical and administrative assistance. During the crisis, PROMESS distributed essential drugs subsidies worth approximately US$2.3 million and made over 5,000 deliveries, with a total value of approximately US$4 million. At the end of the crisis in October 1994, the Centre had stock estimated at roughly US$3 million.

The future for PROMESS

PROMESS is now an accepted part of daily life in the Haitian health sector. The name PROMESS figures prominently in numerous pharmacies throughout the country's various departments. It is found on drug sachets (to be distributed to the sick), on drug data sheets given to health auxiliaries, on reserves in peripheral warehouses and on treatment guides for doctors. PROMESS has been at the heart of a minor revolution aimed at developing a genuine essential drugs programme in Haiti.

While it is difficult to assess the overall impact of PROMESS, a few initial observations should be made. It is generally considered that PROMESS has fulfilled its primary task, by supplying a health network responsible for implementing humanitarian aid programmes. Indeed it is generally considered to have done a lot more besides. The Centre's professional and dynamic approach has firmly established it within the highly strategic supply branch. Through its widespread presence, PROMESS has helped develop other aspects of the Action Programme, such as training schemes, and decentralisation and integration of services. Furthermore, given the fact that most of the Haitian population lacks the money to purchase drugs directly on the private commercial market, PROMESS has given the country's poorest almost unprecedented access to necessary drugs. Without competing unfairly with the private pharmaceutical sector, the Centre has had a regulatory effect on the local market and has helped to raise quality standards.

A supply centre the size of PROMESS is a major asset, particularly in a country where resources are scarce. It promotes financial self-sufficiency in institutions and can have an important impact on the whole Haitian health network. As the driving force behind an essential drugs programme capable of revolutionising patient care and thus transforming the different levels of the health system, the Centre could make a vital contribution to restructuring the Haitian health network. In this respect, discussions undertaken with the authorities and with representatives of various partner organizations will be important for the future of the Haitian health network.

Important decisions concerning the future development of PROMESS have yet to be taken. The aim in all cases should be to turn PROMESS into a distribution facility capable of supplying the entire country. Such a facility could be managed by an executive council consisting of representatives of the authorities, beneficiary institutions and relevant professional associations. That would be an interesting model of joint management, combining the forces of national public bodies, international organizations and beneficiary organizations. ❑

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The contribution of Francine Tardif to this article is gratefully acknowledged.

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NEWSDESK

Philippines: training on rational use

THE international training course on Promoting Rational Drug, Use organized by the INRUD/ Indonesia Core Group, the Action Programme on Essential Drugs, Gadjah Mada University and MSH, held in Indonesia in September 1994, has produced a national offshoot. The INRUD/Philippines Core Group and Philippine National Drug Policy staff recognised the potential of a course promoting rational use to strengthen the implementation of the National Drug Policy and the Generics Law.

In June 1995, 41 participants representing health professionals, local government units and health NGOs, met in Manila to discuss a wide range of topics. These included: frameworks for changing drug use; decision making for rational use interventions; sampling to study drug use; and effective public education. Participants were encouraged to form a network to coordinate rational drug use activities and undertake community studies to improve drug use in their respective regions. ❑

Source: RDU Update 1995: vol 4; no.1. Published by the Philippine National Drug Policy Office, c/o The National Drug Information Centre, Department of Pharmacology, College of Medicine, University of the Philippines, 547 Pedro Gil Street, Manila, the Philippines.

Guide to Good Prescribing – positive feedback

EDM-20 announced the publication of the WHO manual, *Guide to Good Prescribing*, which describes a new method of problem-based pharmacotherapy teaching. The same issue reported on a training workshop in the Philippines, which introduced the concepts included in the manual to 22 pharmacotherapy teachers. A follow-up to the June 1995 workshop was held in November of that year, and showed that in just a few months impressive progress had been made in implementing the *Guide's* recommendations.

In nearly all the Philippine medical schools represented, problem-based pharmacotherapy teaching had been introduced in one or more years of the medical curriculum, either in integrated teaching, as extra hours, by replacing laboratory hours or as a separate course. The perceived strengths of the method were: its relevance to the medical students; that it was less threatening to them by encouraging more discussion than the usual one-way lecturing; and that it promoted a much better interaction between students. Difficulties were: "finding a place in the curriculum", allocating enough curriculum and staff time; and a few resistant senior clinicians.

Participants commented that the development of a personal approach is probably particularly relevant in places such as Asia, where so many drugs are available on the market, and formularies are not yet generally accepted. They also believed that implementation of problem-based pharmacotherapy teaching at all levels will facilitate the establishment of hospital drug and therapeutics committees and the development of hospital formularies.

There was agreement that a five-day intensive training course on problem-based pharmacotherapy teaching and the use of *Guide to Good Prescribing* can have a very positive impact, if supported by senior decision makers. Participants also welcomed the chance of a follow-up meeting, which they believed reinforced the impact and strengthened the interaction between the various universities involved.

A request was made for *Guide to Good Prescribing* to be made available on diskette and e-mail, to allow for local adaptation.

An impact study in Uganda...

"Highly effective in improving students' therapeutic skills". This was the encouraging conclusion reached after a three-week field trial of the pharmacology training methods advocated in *Guide to Good Prescribing*. Organized by the Department of Pharmacology and Therapeutics in the Medical School of Makerere University, Kampala, the study involved 44 fourth and fifth year medical students. Over 90% of those in the study group reported that the training methodology was more practical and relevant to patient care and that it helped them in their clinical examinations. Students have since appealed to other departments in the Medical School to include problem-based training in their curricula. ❑

Source: INRUD News, February 1996.

Copies of ***Guide to Good Prescribing****, WHO/ DAP/94.11 are available from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.15/US$13.50, and in developing countries Sw.fr.10.50.*

Staying alive under five – focus for new child health newsletter

IN order to support health and community workers in tackling child health, the Appropriate Health Resources and Technologies Group (AHRTAG) has begun publication of *Child Health Dialogue*. The newsletter focuses on practical prevention and management of the five main childhood illnesses: acute respiratory infection; diarrhoeal disease; malaria; measles; and malnutrition. The new quarterly replaces AHRTAG's previous child health newsletters, *ARI News* and *Dialogue on Diarrhoea*, and will build on their strengths – providing clear, practical information. New features include regular columns on essential drugs, training tips, simplified research updates and quizzes.

Child Health Dialogue is published in English, French, Spanish, Portuguese, Chinese, Gujerati, Hindi, Tamil, Urdu, Indian English and Vietnamese. The newsletter will be free of charge to readers in developing countries and will cost £12 per year to individuals in Europe, North America, Australasia and Japan. Special rates are available for students, organizations and for bulk orders. ❑

For further information contact: AHRTAG, 29–35 Farringdon Road, London EC1M 3JB, UK. Tel: +41 171 242 0606, fax: +41 171 242 0041, e-mail: ahrtag@gn.apc.org

Director says farewell to DAP

Photo: WHO/D.A. Fresle

MRS Margaretha Helling-Borda, Director of the Action Programme on Essential Drugs for the last two years and a long standing WHO staff member, retired at the end of April 1996. She is pictured above, on her final day in DAP, holding flowers sent by colleagues from the WHO Regional Office for Europe. Friends and colleagues from all over the world sent best wishes to Mrs Helling-Borda for a happy retirement, although few doubt that she will continue to play an active professional role, albeit in a different capacity. Dr Jonathan Quick, who joined the Action Programme in 1995, has been appointed Director. Dr Quick is known to many as the editor of *Managing Drug Supply*[1] and for his work on rational drug use and drug financing. ❑

1. Ed. note: A second edition of *Managing Drug Supply*, published in collaboration with the Action Programme on Essential Drugs, will be published at the end of 1996.

Getting together: African RUD groups strengthen ties

A DAP-supported meeting in Malawi in November 1995 saw the beginning of closer regional collaboration between three African networks concerned with the rational use of drugs. Many members of the Society for Clinical and Experimental Pharmacology for Preferential Trade Agreement Countries (SOCEPTA), the Drug Utilization Research Group in Africa (DURG-AFRO) and INRUD are already affiliated with the other two networks. They therefore welcomed the chance to discuss developing common goals and methodologies, ways to exchange experiences and opportunities for collaborative links. It was agreed that INRUD-Africa regional meetings will be scheduled jointly with SOCEPTA and DURG-AFRO every two years and that *INRUD News* would be used as a forum for *SOCEPTA News*. ❑

Source: INRUD News, February 1996.

NEWSDESK

Teaching pupils about medicines: has the new French initiative got it right?

B. Minzes*

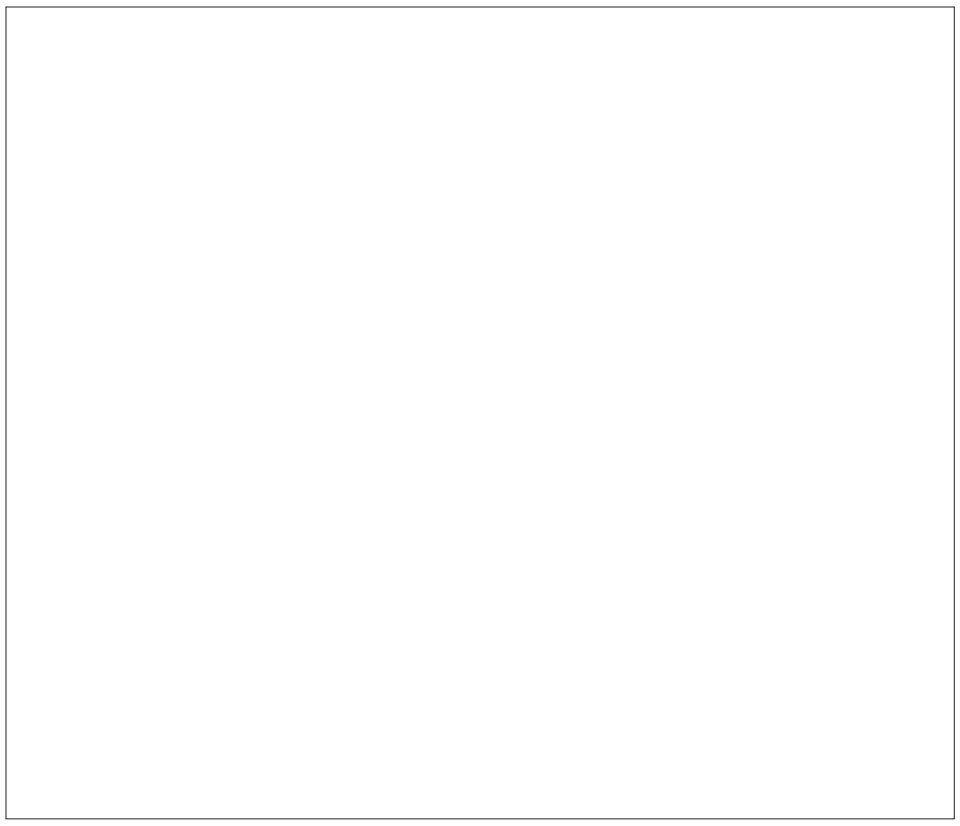
WHAT do schoolchildren of nine to 11 need to learn about medicines? "*Le Bon Usage du Médicament*", a kit produced collaboratively by the French consumers' organizations, physicians' and pharmacists' associations and the national pharmaceutical industry association (SNIP), is a beautifully illustrated and well-presented set of curriculum materials. Does it provide children with the basic information they need in order to use medicines well?

The information in the kit is straightforward and clear. There are worksheets to fill out and an amusing cartoon to read, with stories about children giving each other medicines when they shouldn't, taking extra spoonfuls of good-tasting medicines and otherwise illustrating how not to treat medicines. It is a good presentation of the basic principles of compliance: how to use medicines as directed, avoiding sharing prescribed medicines with friends or family, and keeping a well-ordered family medicine cabinet to avoid accidental misuse. The kit also covers different types of medicines and whether they are curative, preventative, diagnostic or relieve symptoms of disease.

The fundamental problem, especially in the materials directly for children, is what is missing: the idea you might be sick and not need a medicine; the idea you might visit a doctor and leave without a prescription; the idea that medicines can cause harm as well as bringing benefits; the idea that children and parents might ask questions about a prescription; and the broader underlying concept of partnership in health care – that patients can move beyond being passive recipients of doctors' instruction to taking part in discussion and joint decision making on treatment options; and the critically important information that two medicines with different names (brand names) may contain identical substances.

Since the children receive no negative information about medicines, the recommendations to comply with a doctor's instructions are a little thin on WHY. Nowhere does a child read that medicines should not be shared or treated like sweets because they can be dangerous.

A "chain of cure" is presented, discussing symptoms of disease, the parents' role in deciding whether to take a child to a doctor or not, the role of the doctor in diagnosing a disease and prescribing a medicine and the role of the pharmacist as dispenser. The most surprising part of this text is that it gives the impression that every single doctor's appointment ends in a prescription. Elsewhere as well, in a worksheet asking children to describe a sickness and a visit to the doctor, the question is not, "Did the doctor prescribe a medicine?" but "What medicine did the doctor prescribe?".



The kit, which is available in French only, includes cartoons on various aspects of treatment

The background materials for teachers do include a section on the label which mentions side effects, contraindications and interactions, and an explanation that medicines cannot replace good diet, hygiene and adequate sleep and exercise. However, even this section skirts the idea that some common diseases are self-limiting and there is no need for a "pill for every ill".

What do children of nine to 11 need to learn about medicines? They need to learn to use the right medicine as directed and "*Le Bon Usage du Médicament*" will teach them this. They also need to know they have a right to ask questions about medicines and to get answers they can understand. And they need to know that medicines are not magic potions: that they can treat some illnesses very well and others not at all; that they can be potent cures but can also be ineffective; that they can be very helpful but also very harmful. ❑

* *B. Minzes, Publications and Information, HAI-Europe, Jacob van Lennepkade 334 T, 1053 NJ Amsterdam, the Netherlands.*

COURSES

Improve your drug supply management skills

THE International Dispensary Association (IDA), of the Netherlands, and Management Sciences for Health, of the USA, are joining forces in Amsterdam to run a course on Managing Drug Supply for Primary Health Care. The aim is to expose participants to modern management principles of drug supply systems, and to teach them how to apply these in their own situations.

The approach will be highly participatory to facilitate an exchange of views and experiences between senior level staff. Major topics will include: national drug policy; selection and quantification of drugs; procurement methods and strategies; quality assurance; kit distribution; financing drug supply; store management; inventory control; distribution strategies; rational drug use; drug supply management information systems; and indicator based assessments.

The course will take place from 30 September to 11 October, 1996. It is intended for physicians, pharmacists, senior health system managers, and technical assistance professionals from ministries of health, nongovernmental organizations and donor agencies.

The total fee of US$4,500 includes tuition, field trips, accommodation and most meals. ❑

For further information contact: Ellen van den Heuvel, IDA Foundation, P.O. Box 37098, 1030 AB Amsterdam, the Netherlands. Tel: +31 20 4033051, fax: +31 20 4031854, e-mail: ida_sale@euronet.nl

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South Africa: pharmacotherapy teaching course

THE first African Problem-based Pharmacotherapy Teaching course is to be held in Cape Town, South Africa from 25 November to 6 December 1996. The course will be run by the Pharmacology Department of the University of Cape Town in collaboration with the Action Programme on Essential Drugs and the University of Groningen, the Netherlands, which developed the course (see EDM-20). The aim is to teach university teachers of therapeutics and pharmacology how to equip their students with the skills needed for rational use of drugs.

The course registration fee is US$2,900, which includes all course materials, accommodation and meals for the two weeks but excludes travel costs. ❑

For further information contact: Julia Stallard, Postgraduate Conference Division, UCT Medical School, Anzio Road, Observatory 7925, Cape Town, South Africa. Tel: +27 21 406 6407/406 6911; fax: +27 21 448 6263; e-mail: julia@medicine.uct.ac.za

A reminder that the Groningen pharmacotherapy teaching summer course takes place in August each year. *Further information is available from: Department of Clinical Pharmacology, University of Groningen, Bloemsingel 1, 9713 BZ Groningen, the Netherlands. Fax: +31 50 3632812; e-mail:summercourse.pharmacol@med.rug.nl*

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Promoting rational drug use

THE next INRUD/DAP courses on Promoting Rational Drug Use will be held in: Dhaka, Bangladesh, from 2–13 December 1996; and Tanzania in Spring 1997. ❑

For further information contact: Management Sciences for Health, 1655 N. Fort Myer Drive, Suite 920, Arlington VA 22209, USA. Tel: +703 524 6575, fax: +703 524 7898, e-mail: inrud@msh-dc.org

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Second course on drug policy issues

BOSTON University's Center for International Health, in collaboration with the Action Programme on Essential Drugs, is to hold its second course entitled, "Drug Policy Issues for Developing Countries". The course, which takes place in Boston from 17–28 February 1997, is intended for policy makers, senior managers responsible for pharmaceutical systems in developing countries and senior officials of donor agencies. ❑

For further information contact: Dr Richard Laing, Center for International Health, Boston University, 53 Bay State Road, Boston MA 02215-2101, USA. Tel: +617 353 4524, fax: +617 353 6330, Telex: 200191 BUUR, e-mail: cih@bu.edu

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Effective drug management

THE next course on "Effective Drug Management and Rational Drug Use", is to be held from 12 May to 11 July 1997, at Robert Gordon University's School of Pharmacy, Aberdeen, Scotland, UK. (See p. 5 for more details and contact address). ❑

MEETINGS

Informing children about medicines

THE United States Pharmacopeia is sponsoring an open conference, "Children and Medicines. Information isn't Just for Grown-ups", from 29 September to 2 October 1996, in Reston, Virginia, USA.

The Conference aims to generate awareness among health providers, health educators and the public of the need to develop methods to increase understanding of medicines by children and adolescents in their roles as consumers, patients, family members, research subjects and students. ❑

For further information contact: Patricia J. Bush, Consultant, The United States Pharmacopeial Convention Inc., 12601 Twinbrook Parkway, Rockville MD 20852, USA. E-mail: pjb@usp.org

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Pharmaceuticals and GATT: HAI seminar

HEALTH Action International has been asked by many concerned parties to produce briefing materials on the implications of GATT for pharmaceutical policies and the provision of essential drugs in the developing countries. HAI is therefore organizing a seminar, "GATT, Pharmaceutical Policies and Essential Drugs", in Bielefeld, Germany on 4 October l996. This seminar will cover:

- trade related aspects of intellectual property rights (TRIPS) and their effects on pharmaceutical patents;
- the effect of GATT on prices and availability of essential drugs;
- the influence of GATT/WTO on national regulatory authorities;
- possible strategic options.

Speakers and resource persons will include experts on GATT and pharmaceuticals from WTO, WHO and NGOs from developing countries. Two important objectives of the seminar are to form a working group and action plan, and to produce a briefing paper on related issues after the seminar. ❑

For further information contact: HAI-Europe, Jacob van Lennepkade 334T, 1053 Amsterdam, the Netherlands. Tel: +32 20 683 3684, fax: + 31 20 685 5002, and e-mail: hai@hai-antenna.nl

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Improving the use of medicines

STRATEGIES to improve the use of medicine are an increasing priority for national health services and national drug policies. For many international agencies, universities and NGOs they are also a priority area of work and research. The importance and topical relevance of the subject are reflected in a first International Conference on Improving the Use of Medicines, to be held in Chiang Mai, Thailand, from 1–4 April 1997, organized by INRUD, the INRUD national group, and the Thai Ministry of Health, in collaboration with the WHO Action Programme on Essential Drugs and others.

Bringing together policy makers, managers and researchers, with representatives of international agencies, consumer organizations and industry, the meeting aims to synthesize evidence for success of different interventions, develop policy guidelines and identify areas for future research on improving the use of medicines. ❑

For further information contact: ICIUM Conference Organizing Committee, College of Public Health, Chulalongkorn University, Institute Building 3, 10th Floor, Chula Soi 62, Phyathai Road, Bangkok 10330, Thailand. Tel: +66 (2) 2188187, fax: +66 (2) 255 6046, e-mail: chitr@chulkn.car.chula.ac.th

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Coming up: 25th European Symposium on Clinical Pharmacy

THE European Society of Clinical Pharmacy's (ESCP) symposium, "Optimising the Pharmacotherapy Process" will take place in Lisbon from 9–11 October 1996. The meeting will emphasise the need for a multidisciplinary approach and the interrelationship between disciplines in developing pharmacotherapy in the context of total disease management.

Looking further ahead to 21 May 1997, the ESCP will host a three-day conference in Amsterdam, the Netherlands entitled, "Disseminating Drug Information". The Conference will offer numerous workshops, where participants can discuss and formulate standards for responsible provision of drug information. The emphasis will be on the dissemination of information through drug bulletins, scientific publications and formularies, the non specialist press and the Internet. The role of drug information in politics as well as pharmaceutical care will also be discussed ❑

For further information contact: International Secretariat, European Society of Clinical Pharmacology, Parallelboulevard 214 D, 2202 HT Noordwijk, the Netherlands.

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International Congress of Public Health Associations

"HEALTH in Transition: Opportunities and Challenges", is the topical theme for discussion at the 8th International Congress of the World Federation of Public Health Associations. Sponsored by WHO and UNICEF, the Congress will be held in Arusha, Tanzania, from 12–16 October 1997. The World Federation of Public Health Associations is a nongovernmental organization, composed of national public health associations from 48 countries around the world. Participation at the Congress is open to all, and health practitioners, policy makers, administrators, development workers, researchers, and many others from governments, academia, international and nongovernmental organizations are expected to attend. ❑

For further information contact: World Federation of Public Health Associations' Secretariat, c/o APHA, 1015, 15th Street NW, Suite 300, Washington DC 20005, USA. Fax: +202 789 5681.

NETSCAN

Introducing DAP's homepage

THE Action Programme on Essentials Drugs' homepage on the World-Wide-Web service on the Internet offers the user a range of information on the functions and activities of the Programme. This information, which is frequently updated, introduces users to the essential drugs concept, national drug policies, and the work of WHO and the Action Programme in developing countries.

The titles of selected WHO, DAP and other pharmaceutical publications are available on the homepage, to increase awareness of available resources.

The actual content of carefully selected publications can be viewed. For example, feature articles from the English version of the *Monitor* are available from issue 19 onwards and users can also obtain and print out the Guidelines for Drug Donations (see p. 6).

You can find DAP's homepage on the WWW: http://www.who.ch/programmes/dap/DAP_Homepage.html

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AHRTAG Update – Primary Health Care Current Awareness Service, 1996

A current awareness service focusing on primary health care and disability issues in developing countries is now available on line, from the Appropriate Health Resources and Technology Action Group (AHRTAG).

AHRTAG Update, published 10 times a year, describes 150–200 new materials added every month to AHRTAG's bibliographic database. The database includes articles, books, manuals, reports, and unpublished materials on a wide range of issues. Among these are: adolescent health, evaluation, health education, HIV and AIDS, planning and management, programme implementation, structural adjustment and training.

AHRTAG Update lists materials focusing on the practical aspects of primary health care and community-based rehabilitation. ❑

Price: £52/US$104. For further information and subscription details contact: Resource Centre, AHRTAG, 29–35 Farringdon Road, London EC1M 3JB, UK. Tel: +44 171 242 0606, fax: +44 171 242 0041, e-mail: ahrtag@gn.apc.org

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PAHO Web Server

THE Pan American Health Organization (PAHO) has launched its Web Server, containing information on public health and related issues in the Americas. You can visit the Web and Gopher servers at: http://www.paho.org ***or*** gopher://gopher.paho.org ***or*** webmaster@paho.org

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Drugline on CD-ROM

THE work of the Drug Information Centre at Huddinge Hospital, Sweden and the production of its database, Drugline, was described in EDM-14. Drugline is a full text question and answer database containing evaluated and problem-oriented drug information. The documents in Drugline deal with a variety of therapeutic drug problems, such as adverse effects, choice of drug, drug interactions and drug use during pregnancy or breast feeding. Online since 1984, a CD-ROM version of Drugline is now available. The retrieval software used is SilverPlatter's SPIRS, the same programme as for Medline on SilverPlatter, and available for DOS, Windows, MacIntosh and UNIX.

The Drugline CD contains 7,500 documents and is updated six monthly. So far the language is mainly Swedish, but more than 1,000 of the recent questions have been written in English and the percentage of English documents will increase. This type of problem-oriented drug information, produced by clinical pharmacologists and pharmacists, might serve as a model for building up drug information services in developed and developing countries. The information offered can be used as a basis for answering questions and producing similar national bilingual databases. Experience at Huddinge has shown that similar problems relating to drugs tend to be asked frequently and similar problems arise in most countries. Answers to previous consultations can prove useful and save time. The Drugline model is one way to increase efficiency and solve the retrieval problem.

Test via Internet

The Drugline CD-ROM is produced by the Drug Information Centre at Huddinge Hospital in cooperation with the SilverPlatter partner, Info-Nordic. Anyone who wants to test the Drugline CD-ROM can do so via Internet – WWW address: http://www.infonordic.se

For further information contact: Birgitta Öhman, Drug Research and Information Centre, Department of Clinical Pharmacology, Huddinge Hospital, S-141 86 Huddinge, Sweden. Tel: +46 8 746 1066, fax: +46 8 746 8821, e-mail: birgitta.ohman@pharmlab.se

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UK: computer aid to rational prescribing

IN a further move to encourage rational prescribing in the UK, the National Health Service (NHS) Executive is testing a computer-aided prescribing guide which offers the GP three alternative drug treatments for each diagnosis. The system – called PRODIGY (Prescribing Rationally with Decision-support in General Practice Study) – will be tested in 100–150 GP practices throughout the country.

The treatments, which were drafted by a clinical pharmacologist and a doctor, have been validated by the Royal College of Physicians, the General Medical Services Council (the doctors' negotiating body) and the Royal Pharmaceutical Society. The choices are based on effectiveness rather than cost. PRODIGY is in line with the Department of Health's move to promote "evidence-based medicine" with a need for an "effectiveness index" to help doctors make appropriate therapeutic choices. ❑

Source: Scrip No.2070, 1995.

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The need for public health pharmacy: ongoing E-Drug debate

A number of individuals interested in public health aspects of pharmaceuticals have begun an electronic discussion using the E-Drug list server at Healthnet. The focus is on the concepts involved in public health pharmacy and the need for specific training programmes in this area. Anyone with Internet access wishing to contribute further thoughts to the discussion can e-mail: e-drug@usa.healthnet.org

To subscribe to the E-Drug listserver and automatically receive all future correspondence, send a message to: majordomo@usa.healthnet.org

The following command should be the ***only*** line in your message: subscribe e-drug

NATIONAL DRUG POLICY

South Africa's new National Drug Policy

Minister of Health, Dr Nkosazana Dlamini Zuma talks to Essential Drugs Monitor Editor, Daphne Fresle, in Geneva

Daphne Fresle: Why did South Africa decide that it needed a national drug policy?

Dr Zuma: Firstly, South Africa was facing a situation where its drug prices were amongst the five highest in the world. Secondly, the majority of our people did not have access to health care, which was limited to just a few. Thirdly, we were faced with the same budget that was used to provide health care for the few but we had to stretch this to provide for everybody. This meant that we had to reprioritise and we had to make sure that whatever we did was cost effective. One of the major expenditures in our health services, obviously, was drugs. But because there was no drug policy, and hence no coordinated rational strategies of the type that we are now targeting, the cost of health care was constantly being pushed up. We therefore decided that amongst other things we needed a drug policy to be able to regulate some of the activities of health workers, of pharmacists and of the industry, and to also make sure that we were able to provide a core of essential drugs to the health services at an affordable price. Those are really the major reasons why we decided we needed a drug policy.

DF: They are very fundamental reasons, aren't they? Having decided that you needed a drug policy how did you go about its development?

Dr Zuma: Before the elections the different factions had developed their own vision of what they would do if they came into office. And the organization to which I belonged, the African National Congress, had worked on its own policy development. So when we were elected, we looked at that policy to see how it could be applied in government. If we had just wanted a process involving government then the easiest way would have been to take a number of people from across the country and form them into a committee to review the issues and produce a policy. But we considered that such a committee, alone, would not have all the ideas or the necessary experience. We therefore wanted, in addition, a wider approach that would involve consultation with all the stakeholders of the country. We also thought it essential to get information about international experience, because we considered that although we were the last to be free we had to use some of the advantages of being last. This meant learning from people who had gone before us, in two ways: first, learning how and what has worked, and second, learning what has not worked and what we should avoid. This doesn't mean that you never make mistakes but at least you are enriched by the experiences of other people.

So this Committee undertook a very wide consultation process, which included international expertise, such as that of WHO. It then developed a framework that we could use. This was presented to the Minister and to all the members of provincial health executives. Their contributions led to some modifications and strengthening of the policy, which was formally adopted by the Government in January l996.

DF: You talked about learning from the lessons and experiences of others. Did you encounter any problems yourself in this policy development process? I ask this because stakeholders sometimes have very divergent views of where they want to go or a country to go.

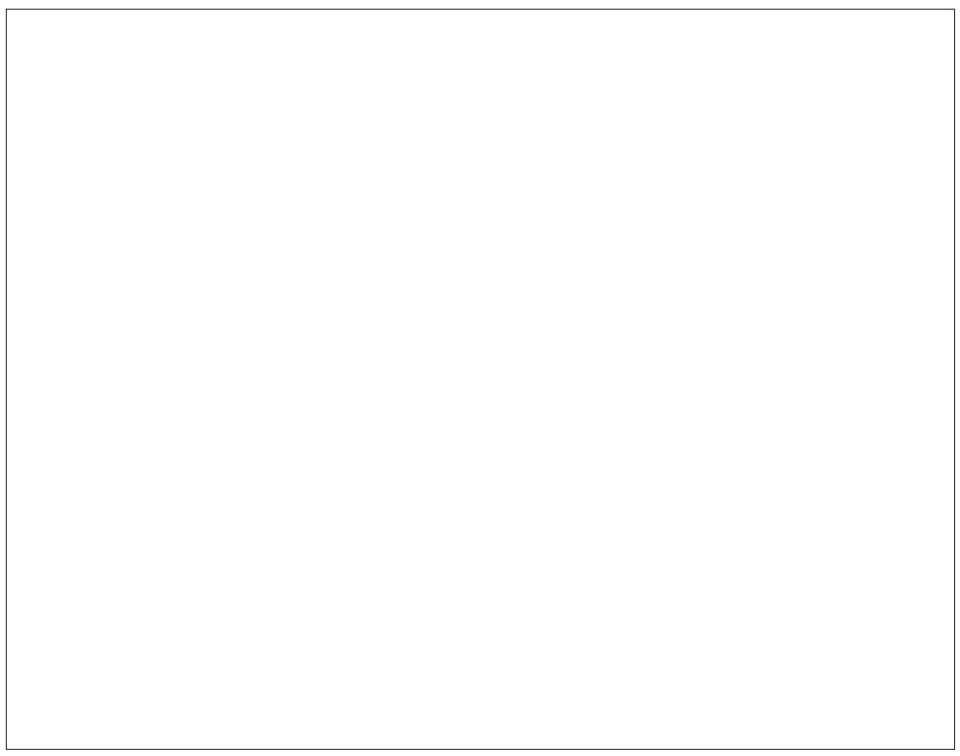


Photo: WHO/D.A. Fresle

Checking drugs at a health facility in Bophuthatswana

Dr Zuma: Well yes! As you can imagine the pharmaceutical sector is an area where there are lots of vested, entrenched interests. And the different stakeholders don't necessarily have the same goals and the same interests. So there were problems in the development process and I'm sure that there are going to be problems in implementation. In fact, there are going to be problems all the time. But I would say that the main difficulties came from three directions. First, as you can imagine, they came from the manufacturers in the sense that they thought the policies were not in line with what they are in business for, which is really just to make the most profit. They considered that parts of the policy were prejudicial to their interests. When asked what they would like to see happen, they said to me initially that they would prefer everything to be left to market forces. However, market forces push up the cost of health care and also the prices of drugs, so I had to reject this position. As a result, there are still aspects of the policy that they are not happy about. I have also had to point out that, although the drug policy is new for South Africa, as a matter of strategy, it does not contain anything which is new, or untried elsewhere. It consists of policies that are implemented in other countries. In fact, our drug policy is still much milder than some of the drug policies that are implemented in the countries of origin of those same manufacturers who are critical of the South African approach.

Other controversial areas relate to the policies governing retail pharmacy and also whether doctors may dispense drugs.

DF: You have quite a lot of dispensing doctors in South Africa, don't you?

Dr Zuma: Yes we do. But, of course, where there is a real need for the doctor to dispense they must continue to do so. To me that is when patients do not have a pharmacy within walking distance and would have to pay for transportation to get their prescription. In these circumstances, I think it is justified for the doctor to dispense. But where there are a lot of pharmacies around, I don't see why doctors should dispense. And in terms of pharmacies, I also think that they should be able to substitute generic drugs for each and every drug a patient is prescribed, and that they should inform the patient of the benefits.

DF: And that is included in your policy isn't it?

Dr Zuma: Yes, it is. I also think that we should be able to open up ownership of pharmacies to people other than pharmacists. There should not be a monopoly and competition helps. I start from the premise that pharmacists are first and foremost professionals before they are business people because if they really wanted to do business they would not have studied pharmacy. But obviously if someone who is not a pharmacist owns a pharmacy you must make sure that there is a pharmacist employed.

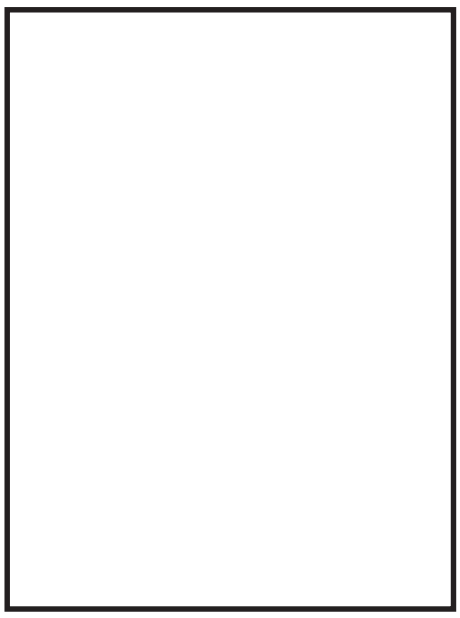


Photo: B. Clark

Dr Nkosazana Dlamini Zuma

So those are some of the difficulties we encountered. We also knew that it was important to gain the support of the general public; to keep them informed about what we were doing, why, and the potential benefits.

DF: And how are you undertaking that sort of advocacy?

Dr Zuma: We are developing an information, education and advocacy project that will develop materials, identify channels of communication and partnerships, to explain such concepts as essential drugs lists and other drug policies, and why it is important to support this work. The heart of the message, the bottom line, is that we are trying to make drugs affordable so that health care is accessible to the majority and not just a minority.

DF: Because the availability and quality of health services, and whether you can afford them, is of great concern to people, isn't it? When I am in South Africa, people in the community – even those who are economically privileged – often express their concern about the price of drugs and the rising cost of health care. It certainly seems to be an important issue for very many people.

Since we are talking about important issues, what would you say are the core issues underpinning the new policy and what will you be giving priority to?

Dr Zuma: Well, we are going to give priority to the use of essential drugs, particularly in primary health care, because that is where we started, although

cont'd on pg. 18

Minister... cont'd from pg. 17

we intend to develop an essential drugs list across the board. But our priority for now is primary health care. That is one major issue. The second issue is replacing the mark up on drugs by a professional fee for the pharmacist because part of the problem is the current huge mark up.

We should also like to know the exit price of the drug from the manufacturer. At the moment there are different prices according to whether the drug is ordered by a pharmacy or by a private doctor. We consider that there should be one price. We also consider that this price should be transparent so that we know what the mark up is between the exit price from the manufacturer and the price that is paid by the patient. The other priority obviously is to encourage generic prescribing and generic substitution. At present most people don't even know that for the same illness you may be prescribed the same pharmacological substance but under different brand names and very different prices. Those are the major priority areas in our drug policy but of course there are lots of other other issues.

DF: You mentioned at the beginning of our discussion that South African drug prices are amongst the highest in the world. I assume that the generic substitution policy you mention is one strategy to bring down prices. Are there any other steps that you are thinking of taking?

Dr Zuma: Well, we would also like to be able to import drugs if we can't get them reasonably priced in South Africa.

DF: Do you mean parallel imports?

Dr Zuma: Yes, because it doesn't make sense to continue paying an unreasonable price if you can pay a reasonable price for the same product imported from elsewhere. As far as I am concerned, that is a ball which is in the manufacturers' court. If they don't want us to implement parallel import then they must give us these different prices. So it is entirely up to them whether we implement this policy component or not.

DF: And talking about implementation, how far have you progressed with this? Of course the policy is in its very early days and has only recently been formally announced. But I know that you have already drawn up and issued an essential drugs list and treatment guidelines for primary health care workers.

Dr Zuma: Yes. We started implementing the essential drugs list as from April this year. To implement some of the other steps we have discussed we will need to change regulations and legislation. The latter is a longer process, particularly at the present time in South Africa, because so many laws are changing and so many new laws are coming into view. But we hope that by next year we shall have most of the legislation and regulations in place. But where such change is not necessary, we are implementing almost immediately.

We are also establishing our own South African Drug Action Programme, which will play a major advocacy role and will also deal with any issues that arise from the implementation of the drug policy that need clarification and attention. The Programme will provide feedback on what's happening at the grassroots level. So its role will be not only to facilitate the implementation of the policy but also to monitor what's going on in terms of results, opinions and actions of stakeholders.

DF: You mentioned earlier some of the difficulties and the reactions from different groups of people. I wanted to ask you specifically about the responses of the main stakeholders to the new policy. They were involved in its development, but nevertheless it's a consensual document and as such can't meet all the wishes of every group.

Dr Zuma: Well, that is true. But interestingly enough there is a lot of support for it. It was clear at the launch of the policy that many doctors are supportive, although they also argued that doctors be allowed to continue dispensing where there is no nearby pharmacy. The main objections of the manufacturers were to parallel import and generic substitution. But basically, as I said earlier, my view is that I won't need to implement parallel import if they give me reasonable prices. It is up to them. The pharmacies obviously are not happy about doing away with the mark up on drugs. But we can't expect that all the aspects of the policy will please everybody equally.

DF: And is the public very happy with the new policy?

Dr Zuma: The public is happy but I think that the public will only be ***very*** happy when prices start to go down.

DF: Yes, people want visible action and results to follow statements of good intent, don't they? But how quickly you can produce results will depend not only on good policy formulation but on the sort of constraints you are facing in implementing the policy. I don't mean now the attitude of different stakeholders, but rather constraints such as the availability of human resources or finances, or perhaps conflicting priorities.

Dr Zuma: Well, human resources are always an issue, at two levels. First, just the critical mass of physical human resources, second, the need for trained people able to implement the policy properly, particularly at the primary health care level. We need to train people, for instance, to use essential drugs appropriately and to follow the treatment protocols. Second, there is a problem with the distribution of retail pharmacies since most of them are in the centre of cities, and are rarely found further afield.

Another major issue is the need to set up good distribution chains, particularly in rural areas. Management skills are also needed: making sure that people don't only re-order essential drugs when they are taking the last tablet out of the container but have a stock in reserve. Health workers also need to be able to predict when stock will be used up more quickly and an urgent order is needed, for instance in the case of a particular disease outbreak. These things are still going to take a long time. Also, most staff are not used to generic prescribing and it will take time to change that, and to update their skills and familiarise them with the international nonproprietary names of the products they use, and so on. So these are some of constraints we are facing.

DF: Getting back to priorities for a moment... there is so much happening in South Africa and – for very obvious reasons – many policy changes, what degree of priority would you say that the drug policy has in terms of your health sector and other national reforms?

Dr Zuma: Well, it has to have a high priority because I'm trying to make health care accessible and affordable; the drug policy is a very vital component of that.

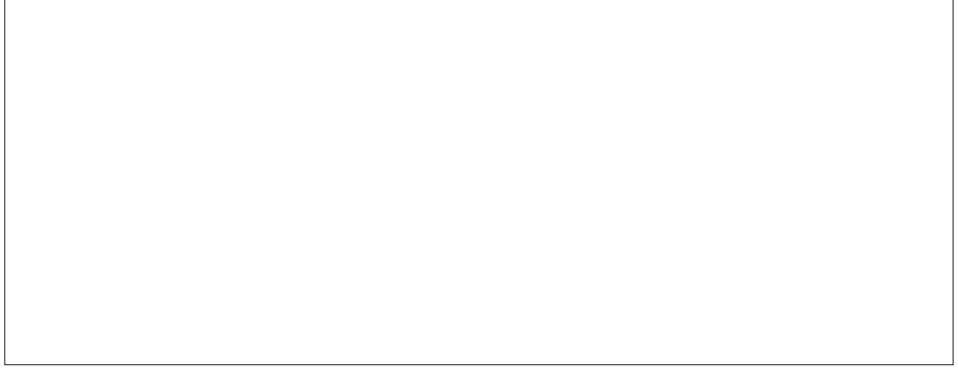


Photo: WHO/D.A. Fresle

People wait their turn at a clinic. South Africans are having to be patient as the country's many reform processes are implemented. The Government has gained support for the National Drug Policy by keeping the public fully informed about its content and potential benefits

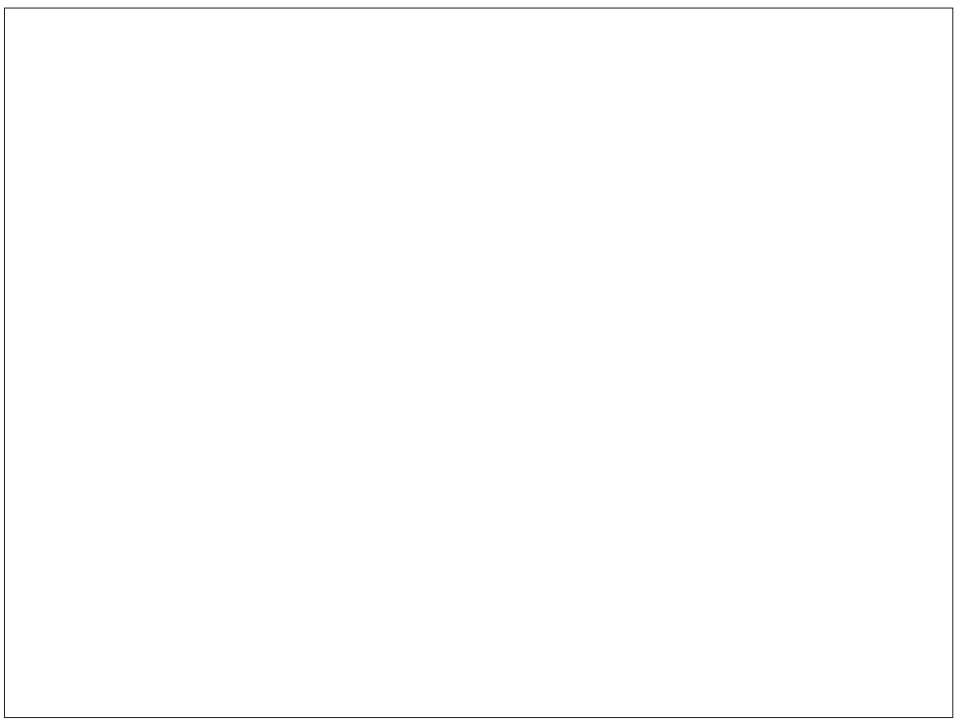


Photo: WHO/D.A. Fresle

A patient receives his prescription at a rural health clinic. South Africa is giving priority to the use of essential drugs and is increasing training in generic prescribing

DF: One of the priorities in the work of the WHO Action Programme on Essential Drugs is to provide technical support to Member States in the development and implementation of national drug policies. As you know, we have been working closely with South Africa in this area and I wonder what you feel that this collaboration has brought to your policy development process?

Dr Zuma: It has been very helpful. First of all, even when there is national expertise, it is always reassuring to have access to other expertise. This is particularly true of an organization such as WHO which not only has extensive technical knowledge but also a global view of what is happening, what has been tried and what has worked elsewhere. And so, when you bring in WHO, you are actually almost bringing in the world's experience on those issues. I think that is a very valuable input to policy making.

DF: Drug policy development often involves so many sensitive issues and many strong opinions, that it can also be helpful to have a neutral voice – such as that of WHO – in this sort of consensus reaching.

Dr Zuma: Well I would say both 'yes' and 'no'. Neutral in terms of the dynamics in the country and the relationship between the different stakeholders, but I would hope that you are not neutral about the principles of providing health care in an equitable and accessible way.

DF: Quite! WHO is not neutral about those fundamental principles, of course.

Before we close, is there anything else that you would like to add in conclusion?

Dr Zuma: Well perhaps just to say that having a drug policy is really a minute step towards what we want to achieve. The real test is in implementation. I hope that WHO and other people in health care in the developed world who have helped us so far are not going to tire... that they will help us through the difficult route of implementation and solving problems that we may find along the way.

DF: I can assure you that the Action Programme won't tire; providing such support is what we are here to do. Thank you very much indeed for discussing so openly your experience, plans and goals. I know that many people, organizations and countries throughout the world are watching developments in South Africa with the keenest interest. ❑

South African National Drug Policy
Rationale and objectives

RATIONALE

Health care delivery in South Africa until the recent process of democratisation and universal franchise was characterised by a two-tier system of: l) private health care funded by medical schemes, which covered up to 20% of the country's population, the vast majority of whom were from the white section of the population; 2) a public sector which was characterised by fragmentation (no less than 14 health authorities), a resultant irrational use of resources, poor working conditions and inadequate infrastructure.

Although South Africa spent 6.66% of its GNP on health care in 1992/93, public sector expenditure accounted for only 3.44% of GNP, with the private sector taking up 3.22%. Put differently, the private sector was responsible for 48.5% of total health care expenditure in 1992/93. Disparities between the public and private sectors are further illustrated by the fact that in 1990 the private sector was responsible for 80% of the country's total expenditure on drugs, although 60/70% of the total volume of pharmaceuticals was consumed in the public sector.

The pharmaceutical sector, as a component of the health sector, reflected its deficiencies, most notably the lack of equity in access to essential drugs, with a consequent impact on quality of care. Furthermore, rising drug prices, already high in international terms, gave increasing cause for concern, as did evidence of irrational use of drugs, losses through malpractice and poor security, and cost ineffective procurement and logistic practices.

Most of these problems are interlinked. The Government decided to tackle them systematically through the development and implementation of a National Drug Policy that would be consonant with and an integral part of the new National Health Policy, which aims at equity in the provision of health care for all.

GOALS AND OBJECTIVES

The goal of the National Drug Policy is to ensure an adequate and reliable supply of safe, cost effective drugs of acceptable quality to all citizens of South Africa and the rational use of drugs by prescribers, dispensers and consumers. The specific objectives are:

Health objectives...

- to ensure the availability and accessibility of essential drugs to all citizens;
- to ensure the safety, efficacy and quality of drugs;
- to ensure good dispensing and prescribing practices;
- to promote the rational use of drugs by prescribers, dispensers and patients through provision of the necessary training, education and information;
- to promote the concept of individual responsibility for health, preventive care and informed decision making.

Economic objectives...

- to lower the cost of drugs in both the private and public sectors;
- to promote the cost effective and rational use of drugs;
- to establish a complementary partnership between Government bodies and private providers in the pharmaceutical sector;
- to optimise the use of scarce resources through cooperation with international and regional agencies.

National development objectives...

- to improve the knowledge, efficiency and management skills of pharmaceutical personnel;
- to reorientate medical, paramedical and pharmaceutical education towards the principles underlying the National Drug Policy;
- to support the development of the local pharmaceutical industry and the local production of essential drugs;
- to promote the acquisition, documentation and sharing of knowledge and experience through the establishment of advisory groups in rational drug use, pharmacoeconomics and other areas of the pharmaceutical sector.

South African National Drug Policy
Key policy components and strategies

Legislation and regulations

The aim is to ensure that drugs reaching the patients are safe, effective and meet approved standards and recommendations. Strategies include:

- strengthening the Medicines Control Council;
- review of legislation and regulations to support NDP objectives;
- rationalising drug registration, including a five-year re-licensing system for drugs, prioritisation of registrations, based on need, with fast-track procedures for essential drugs;
- dispensing by medical practitioners and nurses only permitted when pharmaceutical services are not available;
- strengthened drug inspectorate;
- establishment of a national drug quality control laboratory;
- drug donation guidelines based on those of WHO.

Drug pricing

The aim is to promote the availability of safe and effective drugs at the lowest possible cost. Strategies include:

- establishment of a Pricing Committee to monitor and regulate drug prices within the Ministry of Health;
- total pricing transparency and a system of nondiscriminatory pricing;
- replacement of wholesale and retail percentage mark-up system by a fixed professional fee;
- drugs at primary health care level free of charge; a fixed, affordable co-payment for drugs at secondary and tertiary levels, with system of exemption for patients without the resources to meet such payment;
- incentives for national production of generic drugs;
- generic prescribing in public and private sectors;
- generic substitution allowed in public and private sectors with pharmacist responsibility to inform patient on related benefits.

Drug selection

The aim is to promote the rational choice of drugs in accordance with the essential drugs concept. Strategies include:

- development of an Essential Drugs Programme, which includes an essential drugs list, for primary, secondary and tertiary levels of care, and standard treatment guidelines.
- use of the national EDL list as a foundation for: the basic health care package of the national health system; procurement and use of drugs; standard treatment guidelines and training in rational prescribing; drug information to health care providers, including a national formulary; support to the national pharmaceutical industry; drug donations.

Procurement and distribution

The aim is to ensure an adequate supply of effective and safe drugs of good quality to all people in South Africa. Strategies include:

- annual budget for drug procurement to be based on proper quantification using morbidity and population data;
- price negotiations in procurement for the public sector to be undertaken at the national level using national and international tendering;
- computerised and standardised tender system;
- monitoring of national tender prices and their comparison with international prices. Government reserves the right to procure on the international market, including parallel importation and purchase on the international generic market;
- improved drug storage and distribution systems;
- promotion of national self-sufficiency in the production of essential drugs.

Rational use of drugs

The aim is to promote the rational prescribing, dispensing and use of drugs by medical, paramedical and pharmaceutical personnel and to support the informed and appropriate use of drugs by the community. Strategies include:

- appropriate theoretical, practical and ongoing training, and revision of curricula to reflect NDP priorities and strategies;
- provision of scientifically validated drug information for professionals and the community;
- establishment and strict enforcement of ethical criteria and guidelines for drug promotion and the inclusion of related issues in all health and pharmaceutical professional curricula;
- establishment of hospital therapeutic committees;
- an enhanced role for pharmacists and their involvement in a multidisciplinary approach to the rational use of drugs.

Human resources development

The aim is to develop expertise and human resources to support the successful implementation of the policy and to promote the concepts of essential drugs and rational drug use to ensure their adoption throughout the country. Strategies include:

- appropriate institutional and in-service training programmes designed and implemented to address specific needs and covering medical doctors, nurses, pharmacists, pharmacy technicians and health service managers;
- focus on skills-based training.

Research and development

The aim is to promote research that will facilitate the implementation and evaluation of the National Drug Policy. Strategies include:

- support to operational research on NDP impact, prescribing and dispensing, economics of drug supply and use, and sociocultural aspects of drug use.

Technical cooperation

The aim is to maximise the effective use of limited resources through technical cooperation with international agencies. Strategies include:

- maintaining and strengthening cooperation with international agencies, such as WHO, in a comprehensive range of technical areas related to pharmaceuticals.

Traditional medicines

The aim is to investigate the use of effective and safe traditional medicines at primary level. Strategies include:

- encouragement of traditional healers to work more closely with the formal health sector;
- investigation of traditional medicines for efficacy, safety and quality; registration and control of marketed traditional medicines;
- establishment of a national reference centre for traditional medicines.

Monitoring and evaluation

The aim is to support the successful implementation of the National Drug Policy through establishing mechanisms for monitoring and evaluation of performance and impact that will identify possible problems and effective strategies. Strategies include:

- use of indicators for monitoring NDP;
- systems for monitoring of the private sector and, to a limited extent, international pharmaceutical markets.

Source: National Drug Policy for South Africa, Department of Health, Pretoria, January 1996.

NATIONAL DRUG POLICY

Meeting health needs through national drug policies

INCREASING population, widening income gaps, changing epidemiological patterns, constrained public budgets, and rising pharmaceutical expenditures are pressing governments in the Asia-Pacific Region, as elsewhere, to find new approaches to ensure equitable access to drugs; rational use of drugs; and quality, safety, and efficacy of drugs. The International Conference on National Medicinal Drug Policies, held in Sydney, Australia in October 1995 provided an opportunity for nearly 300 delegates from 31 countries, mostly from the Region, to exchange experiences in developing, implementing and sustaining national drug policies (NDPs) aimed at achieving these objectives. Throughout the conference small informal gatherings of delegates from various countries and organizations led to new plans for collaboration, follow-up and sharing of experience.

Organized by the Australian Government and the Action Programme on Essential Drugs (DAP), the conference also included, in addition to country delegations, participants from the World Bank, UNICEF, UNIDO; industry associations and individual companies; consumer organizations, such as Health Action International/ Consumers International, other voluntary organizations; professional associations; the Dag Hammarskjöld Foundation; Karolinska Institute; Harvard University and other universities; and non profit organizations, such as the Medical Lobby for Appropriate Marketing and Management Sciences for Health.

The conference theme, "Can a comprehensive approach to national medicinal drug policy meet both health and economic needs?", was explored through country presentations and four concurrent workshops. Participants endorsed an overall set of recommendations on NDPs and the policy process (see summaries in Boxes l and 2). In addition, specific recommendations were developed for each of the four workshop topics: access to medicines; rational use of drugs; quality, safety, and efficacy; and the role of industry (see summaries in Box 3).

Photo: S. Wong/Australian Prescriber

The Expert Panel during one of the conference sessions

Box 1

General conference recommendations

- NDPs should be supported from the highest level of government.
- NDPs should be developed within the context of a national health policy.
- Countries must tailor policies to fit their individual needs, while drawing from the experiences and observed impact of existing policies in other countries.
- Continued regional collaboration is necessary to implement and sustain NDPs.
- Public spending on health should be adequate to ensure a basic level of access.
- NDPs should be developed through an open, participatory intersectoral process involving health professionals, consumers, academia, industry and other concerned parties.
- Adequate financial and human resources are necessary to develop and sustain an NDP.
- The NDP should identify economic mechanisms which foster the achievement of health objectives through the NDP.
- The consequences of international harmonisation, macroeconomic changes, structural adjustment and international trade developments should be carefully evaluated at the international and national levels.

Box 2

Features of national medicinal drug policies

National drug policies should:

- guide resource allocation to improve equity and efficiency in the provision of health care
- be evidence-based and performance-based
- be tailored to individual country's needs
- promote the essential drugs concept in both the public and private sectors
- promote legislation and regulation which is realistic and which can be implemented in the national context
- encourage and empower consumers to play an active role in policy planning and implementation
- encourage social responsibility among public and private health providers, industry and other key implementors
- involve the media and include a media strategy

Access to medicines

In some countries of the Region, government health services are able to ensure access to drugs for a large portion of the population. But in most countries the private sector predominates. High prices and inadequate consumer information limit access to affordable essential drugs. At the same time, government health services face financial pressures and other constraints.

Emphasis was placed on the need for exploring economic mechanisms and incentives to increase access, through both private or public sectors, and to improve public sector efficiency in achieving health objectives. Examples of promising possibilities included the integration of the essential drugs concept in social and community health insurance, incentives to improve access in under-served areas, application of cost effectiveness analysis to pharmaceutical expenditure decisions, price competition through generic dispensing, contracting certain public drug supply functions, and group pharmaceutical procurement for smaller islands of the Western Pacific. At the same time, it was observed that the pharmaceutical market is not fully competitive and that public health interests require a degree of state regulation.

The meeting emphasised that political will is essential for implementation of successful policies to improve equitable access to drugs, particularly for the poor, and that market forces alone cannot guarantee access to needed drugs for the entire population, and should be regulated.

Rational use of drugs

Using medicines appropriately was a major focus of discussion. Since the 1985 WHO Conference on the Rational Use of Drugs held in Nairobi, understanding has increased of the social, cultural, and behavioural determinants of medication use. Building on this wider perspective, progress has also been made in identifying effective strategies and interventions, particularly targeting prescribers. However, interventions to improve drug use – especially those directed to the public – are still often mounted without adequate exploration of underlying causes, a thorough analysis of possible alternative strategies or in-built systems to monitor outcome. Successful interventions often remain unpublished and so can rarely be replicated; and strategies for their dissemination are poorly developed. In many countries the political will to implement programmes to encourage rational use appears to be lacking and specific funds are seldom made available. Other contributory problems cited included that drug promotion is rarely monitored and is not always ethical, and that many consumers lack information about the rational use of drugs.

Participants from Indonesia, Nepal, Bangladesh, Thailand, New Zealand and other countries described the impact of creative approaches to promoting rational drug use, including focused clinical guidelines, district-level self-monitoring, drug audits, doctors' self-audit, interactive patient-provider groups to reduce injection use, and mothers' drug information groups to improve self-medication. The conference endorsed the right of health providers and consumers to objective, understandable drug information.

Quality, safety and efficacy of medicines

Countries noted that there is considerable variation in capacity to ensure the quality, safety and efficacy of drugs on the local market. Inadequacies were cited in drug legislation and regulation; inspection and enforcement; standards for quality, safety and efficacy; use of the

WHO Certification Scheme; export control; information management and exchange; training; and consumer involvement.

Recommendations emphasised the fundamental role of drug registration, inspection and enforcement. The need for adequate human, financial and organizational resources was also stressed. Considerable attention was given to the potential benefits of greater regional cooperation through harmonisation and training in areas such as standards for quality, safety and efficacy; good manufacturing practice; drug evaluation; standards of drug information; and effective communication among countries.

Industry's role

In discussing the role of industry the conference recognised the need to move beyond adversarial approaches to seek the benefits of a socially responsible industry. A senior official of the Australian Pharmaceutical Manufacturers Association observed that, "Industry is ready, willing and able to take up the challenge of demonstrating that health and profit can be put together for the benefit of the consuming public". Presentations from China, Japan, Indonesia, Bangladesh, India, Latin America and ASEAN highlighted various approaches. Concern was expressed about the possible effects on health services, as well as on local industry development, of regional and international agreements on harmonisation of drug registration requirements and of the new world trade agreement (GATT, Uruguay Round), particularly those provisions related to patents.

Although the pharmaceutical industry ranges from small local manufacturers to international corporations the conference identified many common issues. These included the critical importance of good manufacturing practices, a frequent lack of partnership between some of the players involved in national drug policies and large price variations for the same drugs in different countries.

Benefits of broader partnerships

While governments have the central responsibility for developing and implementing national drug policies, the benefits of broader partnerships were illustrated through country experiences. Examples were given in which the development and implementation of NDPs involved all concerned levels of government, health professionals, consumers, academia, industry and other interested parties.

Consumer groups, for example, have contributed through education, advocacy, and technical support. In the cases of Australia and the Philippines, their contribution was crucial in the early stages of national drug policy development.

The value and impact of collaboration within the Region were highlighted with examples of a multi-country assessment of WHO's Ethical Criteria for Medicinal Drug Promotion; a WHO-coordinated comparative analysis of national drug policies and policy indicators; and activities coordinated through Action for Rational Drugs in Asia (ARDA), the International Network for Rational Use of Drugs (INRUD) and Australian-Philippine cooperation.

New vision is needed

The keynote speaker from the Philippines observed that national drug policies must be, "crafted through open, honest, thoughtful and productive development dialogue". NDPs are part of a reform process which "cannot be unilaterally imposed through legislation, regulation, or litigation". Instead they should be developed through true intersectoral collaboration and commitment. Two of the moving spirits behind Australia's national medicinal drug policy observed that pharmaceutical policies have less to do with drugs than with, "achieving a balance between economic growth and social justice, wealth and poverty, regulation and freedom, risk and certainty, incentives and sanctions, costs and benefits, suspicion and trust, isolation and involvement".

The conference also stressed that policies should be evidence-based, drawing on positive and negative experiences from other countries and the documented impact of existing NDPs.

The strength of the conference was that, through a widely representative and participatory process, so many people, from so many countries, with such diverse backgrounds could agree on principles to guide the way forward as well as specific follow-up for regional, intercountry, and national action. This process modelled the open, participatory, intersectoral process which the conference endorsed for NDP development. ❑

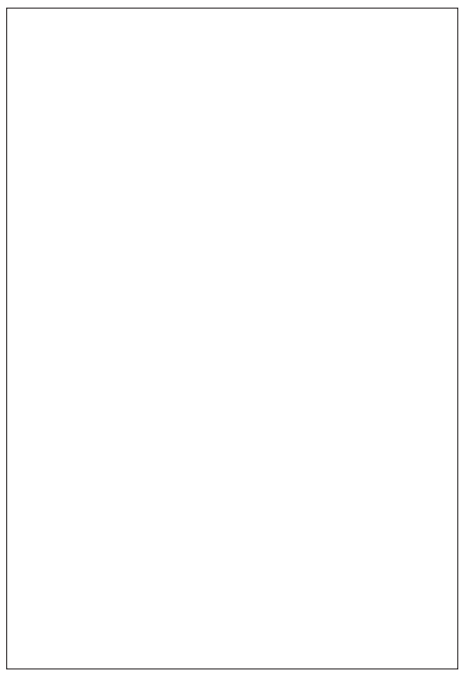


Photo: S. Wong/Australian Prescriber

Dr Bengzon, former Minister of Health of the Philippines, giving the keynote address at the conference

Box 3

Specific conference recommendations

Access to medicines

- Affordability should be promoted through generic drug policies, social and community insurance schemes and creation of incentives for improving access in underserved areas.
- Information should be exchanged on prices, pricing mechanisms and policies, performance of manufacturers and suppliers of essential drugs and raw materials, patterns of drug use and economic analysis.
- Governments should analyse the cost effectiveness of health care interventions, including economic analysis of individual pharmaceutical products where appropriate.
- Governments should ensure effective procurement systems in the public sector.
- Governments should support efforts of non-government organizations to make affordable essential drugs available to low income and other target populations.

Rational use of drugs

- Governments should publicly endorse rational use of drugs.
- National rational use of drugs coordination units should be established with multisectoral advisory committees, qualified staff and an operating budget.
- Rational use of drugs programmes should involve relevant departments in the ministry of health and other ministries, health professionals, academia, industry and consumers.
- Governments should ensure competency-based training for all drug providers including doctors, pharmacists, other health professionals and drug retailers.
- Governments should foster cost effective targeted interventions with measurable outcomes aimed to promote the rational use of drugs at all levels of health care.
- Health providers and consumers have a right to objective and useable drug information provided through health education programmes, the news media and ethical drug promotion.
- National ethical criteria for drug promotion, based on the WHO Ethical Criteria for Medicinal Drug Promotion, should be developed and enforced.

Quality, safety and efficacy of medicines

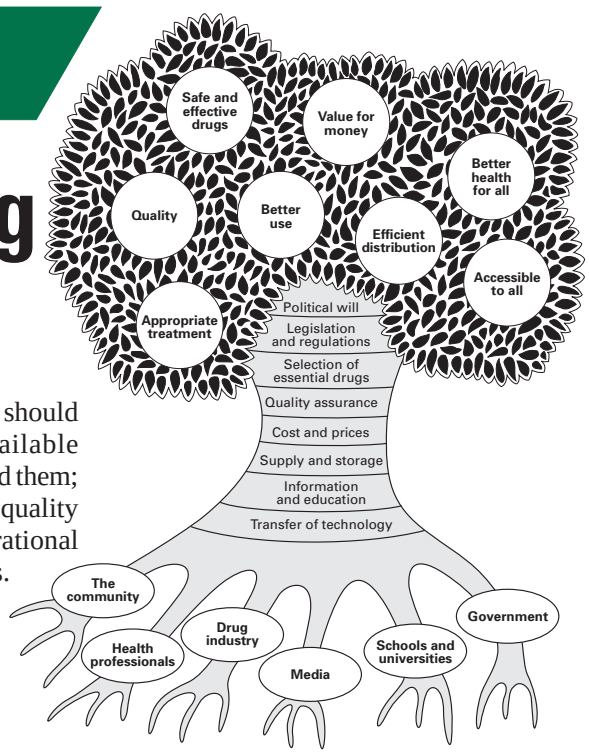
- Registration of pharmaceutical products should be strengthened by development and implementation of guidelines and processes for good regulatory practice.
- Adequate human and financial resources must be allocated to ensure quality, safety and efficacy of drugs.
- Training activities should include academia, government and industry facilities.
- Harmonisation activities within the Region should consider standards for quality, safety, and efficacy; good manufacturing practice; drug evaluation; standards of drug information; and effective communication and collaboration between countries.
- Countries with specific expertise within government and industry should be utilised for the training and upgrading of personnel from other countries.
- The WHO Certification Scheme should be complemented with indicators of its effectiveness, guidelines for implementation, a system for peer review among countries and a system for handling complaints from importing countries.
- There should be adequate drug regulatory controls over exported products by exporting or donating countries.
- The International Conference on Harmonisation should be expanded to allow active involvement by all countries and access by consumer organizations, so as to evaluate its implications for the Region and also to emphasise consumer interests and health policy perspectives.

Industry contribution

- A new paradigm is required which recognises that a socially responsible industry and profitability are compatible. Both industry and national drug policies should recognise a drug as a medication process incorporating honest and full information related to health outcomes.
- Involvement of industry with all partners is essential in the development and implementation of NDPs.
- Industry should work with governments, funders, recipients and providers to improve affordability, availability, and access to essential drugs and drug information.
- Industry should be encouraged to participate in human resource and technical development both within the industry and with the other partners.
- Research and development in the Region as well as development of local industry are desirable.

NATIONAL DRUG POLICY

Developing national drug policies: WHO update



COUNTRIES continue to have serious problems in ensuring the availability and the rational use of drugs. The reasons are complex and linked not only to financial and budgetary constraints but also to the characteristics of the market, the attitudes and behaviour of governments, prescribers, dispensers, consumers and the drug industry.

The experience of many countries has shown that pharmaceutical problems and issues can best be resolved within a common framework. To help in this work, WHO's *Guidelines for Developing National Drug Policies* were published in 1988. They provided an overview of core policy issues and incorporated the essential drugs concept.

The guidelines have been used by many countries in formulating their own national drug policies. However, with experience gained from their use, and rapid global change impacting on the pharmaceutical sector, it became apparent that important new technical issues and developments needed to be addressed in an updated publication. A WHO Expert Committee met in Geneva in June 1995 to provide a contribution to updating the 1988 Guidelines.

The Committee recommended that every country should formulate and implement a comprehensive national drug policy. While goals and objectives would depend upon national circumstances and priorities, their broad thrust should be to make essential drugs available and affordable to all those who need them; to ensure the safety, efficacy and quality of drugs; and to promote their rational use by consumers and prescribers.

A drug policy should form part of a broader national health policy, and whenever possible should emphasise preventive health care. Policy development and implementation calls for a partnership of all stakeholders: government, health care providers, consumers, manufacturers and universities, the Committee stressed.

Key national drug policy issues covered in the report include:

- legislation
- drug selection and supply
- quality assurance
- rational use
- economic strategies
- monitoring and evaluation
- research
- human resource development
- technical cooperation among countries.

The document concludes with guidance on the policy development process, such as priority setting, policy formulation and implementation, monitoring and evaluation.

Policy makers, development organizations and other stakeholders should find the report a useful contribution to pharmaceutical policy development. Additional inputs will be sought to prepare the second edition of the WHO guidelines on developing national drug policy, planned for 1997, which should provide a further practical tool in this area. ❑

*The **Report of the WHO Expert Committee on National Drug Policies**, WHO/DAP/95.9, is available, free of charge, in English and French, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.*

** The highly acclaimed WHO manual, **Indicators for Monitoring National Drug Policies** (WHO/DAP/94.12) will soon be published in French. Available from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.25/US$22.50, and in developing countries Sw.fr.17.50.*

Asia-Pacific: seminar promotes national drug policies

THE implementation of national drug policies in the Asia-Pacific Region was the subject of lively debate at a seminar held in Sydney in October 1995. Organized by Consumers International Regional Office for Asia and the Pacific in collaboration with the Dag Hammarskjöld Foundation, Sweden, the meeting brought together 55 participants. They included members of Consumers International, network partners, health ministry officials, academia, and the media, many of whom went on to attend the International Conference on National Medicinal Drug Policies (see p. 20).

Four broad themes were chosen to reflect some of the main problems countries in the Region face in implementing the major components of national drug policies. The themes were: national drug policies and drug legislation; drug pricing policies; regional cooperation and sharing of information; and economic, commercial and technological developments of the Asia-Pacific Region's pharmaceutical sector. Small working groups discussed these issues, followed by a plenary session to share experiences, problems and successes. The seminar concluded with participants resolved to work together to promote rational drug use and the adoption of national drug policies. They agreed on the need to:

- enact legislation, formulate rules and regulations to make national drug policies and essential drugs applicable to both the public and the private sectors;
- enter into a regional cooperative agreement to enable drug regulators to share relevant and vital information on different aspects of pharmaceuticals;
- regulate, control and monitor prices;
- strengthen the economic, commercial and technological development of the pharmaceutical sector. ❑

LETTERS TO THE EDITOR

Understanding injection preference

Editor,

I was pleased to read in EDM-20 the research article on unnecessary injections in Thailand and additional remarks on polypharmacy. It is necessary to look back about 60 years to find the basic reasons for injection preference.

In Zimbabwe, and I am sure many other Third World countries, western medicine was not perceived as very effective until the arsenicals appeared in the 1920s. These were normally given by intravenous injection for syphilis and with even more spectacular results for yaws. It was so much better than anything which had gone before that many people soon sought the magic. This was succeeded by the sulphonamides, also given by injection, which were also pretty miraculous with lobar pneumonia, the meningitides and gonorrhoea.

The real miracle came in the late fifties with penicillin, which cured all sorts of diseases which had formerly been either fatal or led to long periods of suffering. Penicillin was given by injection, and increasing numbers of people flooded the health service, both private and public.

It was the ***injection*** which was perceived as western medicine's miraculous offering to mankind. Private medical practitioners were able to give more injections than public institutions, and gained a great reputation at that time, despite charging for services which the Government gave free until the mid sixties.

As more and more effective oral medication became available it was ignored by the general populace, even highly educated people. Government institutions naturally followed the world trend away from injections, but most people demanded at least one injection. Their wishes then, and even today, are pandered to by smaller health centres, where staff might feel they could lose credibility among their clientele, and by doctors in private practice, who feel that they can attract custom by being known as injection givers. There is also an unknown number of charlatans who, although completely unqualified to do so, give injections, usually of worthless material through an unsterile needle.

While at first such faith in injections pleased me as it brought many sufferers in for treatment, in the last 20 or 30 years it has been a horror, because nearly every new patient indicates they will not be happy unless they have an injection. The answer seems to be to take the time to explain, on an individual basis, the reasons for not giving an injection and why the patient has come to believe in the value of injections. It is hard going at first, but now in our community hardly anyone wants an injection and returns to our community clinic without going elsewhere to receive an injection.

Polypharmacy...

Some years ago I conducted a small research project amongst the elderly living in their own homes in Harare. We found one old lady who had been prescribed 14 different items, not one of which had to be taken at the same time as another. Seven were thought completely unnecessary, three were to counteract the effects of another of her drugs, and so forth. It was not until she was taken off all medication that she regained her health. The answer to this is continuing in-service training in rational prescribing.

At a time when the Zimbabwe Health Service is under increasing stress because of shortage of funds, more thought needs to be given to spending the little we have in a more rational way. Health professionals should pay more attention to EDLIZ, Zimbabwe's excellent manual on drug treatment guidelines and essential drugs. Prescribers should take patients into their confidence more often. If they were to do so patients would be more likely to leave the health unit confident in their treatment, even with no drugs at all.

—Dr Raymond T. Mossop, (Retired), Former Head, Community Medicine, University of Zimbabwe and Former President of College of Primary Health Care Physicians, 7 Fleetwood Road, Alexandra Park, Harare, Zimbabwe.

Making good use of the Monitor

Editor,

I always enjoy EDM as it gives me so much information. I use a lot of the material from it to help me in writing articles and giving talks.

In Nepal, we have just established a group of journalists and health workers which aims to put the message over to the public that too many drugs are used unnecessarily. For example, large amounts of money are spent on such items as liquid vitamins and tonics. It is almost universal practice in Nepal to take vitamins and tonics while using antibiotics, which are thought to make you very weak. Patients believe it is the only way they will regain their strength.

We are using a variety of media – radio, television and journals – to try to make more people aware of the importance of using drugs rationally. Thank you for helping in our work by sending us EDM.

—Dr Aruna Uprety, Resource Centre for Primary Health Care (RECPHEC), P.O. Box 117 Bagbazar, Kathmandu, Nepal.

Ed. note: Thank you for your letter. It is always both interesting and very useful for us to hear how readers use the Monitor in their work, and we should welcome more examples. You can contact us by post, fax or e-mail (see page 1 for details).

Ethical marketing of drugs

Editor,

We are appealing to your readers in developing countries to send to us at the address below, examples of questionable drug advertisements, drug packages etc. for our "Doctors' Initiative" on ethical marketing of drugs. We are particularly interested in advertising of medicines for children. We should also be very pleased to hear from anyone in Europe who can contribute their experience to our campaign for ethical drug marketing strategies.

—Albert Petersen, Doctors' Initiative – Terre des Hommes and BUKO Pharma-Kampagne, Pharmaceutical Aid Department, German Institute for Medical Missions, P.O. Box 1307, 72003 Tübingen, Germany.

Russian EDM fulfilling a need

Editor,

I read EDM-17 with much interest and pleasure. It contains a great deal of the practical and theoretical information necessary in the day to day work of professionals in the pharmaceutical sector.

I am a teacher in the Pharmaceutical Faculty of the Medical and Pharmaceutical University of the Republic of Moldova. During lectures and practical sessions we teach our students the basics of pharmaceutical information and legislation; marketing and management; and problems related to drug supply and distribution.

Due to the difficult financial situation, the libraries, particularly the Moldova Republican Medical Library, cannot subscribe to foreign pharmaceutical publications, and this is creating an informational "hunger" concerning relevant professional issues.

EDM provides us with current, reliable information on drug policy issues at international level. Could you please ensure that I am on your mailing list.

—Mikhail Lupu, A. Russo str.4, app.23, Kishinev 30, Republic of Moldova.

WORLD HEALTH ASSEMBLY

Drug discussions at the 49th World Health Assembly

PHARMACEUTICAL issues were high on the agenda at the World Health Assembly in May 1996. Globally, the drug situation remained characterised by a polarisation of those with reliable access to essential drugs, who are mainly in developed countries, and those with little or no such access, who are mostly in developing countries, WHO reported to delegates.

Population growth and the rising incidence of tuberculosis, AIDS and other diseases are putting further pressure on already inadequate drug supply systems. Demand is growing while public and community resources are decreasing or static. The private sector is increasingly taking over parts of the drug supply system. The challenge therefore is to help countries make the best use not only of limited public funds but also of private sector resources. More data are needed to determine which methods of drug financing enhance or diminish people's access to essential drugs in developing countries. As free market economies expand and privatisation grows, many countries urgently require new and enforceable drug legislation to meet the changing situation.

Education and training programmes to ensure technical efficiency and management capacity at national level are crucial to the successful implementation of national drug policies but are frequently neglected. Countries also need to tackle the problems of salaries and career development in the public sector, the inadequacy of which is a major contributory factor to staff shortages and low performance levels.

There continues to be an imbalance between commercially produced drug information and independent, comparative, scientifically validated and up-to-date information on drugs for prescribers, dispensers and consumers. Systems for the monitoring of ethical criteria have to be introduced in most countries. Those exporting drugs to developing countries have an ethical responsibility to ensure that drug information, safety and quality meet the standards of the country of origin. Inappropriate drug donations, whether as emergency or other bilateral aid, continue to be a cause of concern.

Direct country support is the highest priority of the Action Programme on Essential Drugs, the Assembly was informed. The number of countries requesting assistance is rapidly increasing. Technical and financial cooperation has been provided to some 60 countries. Underlying this country support is the development of practical tools and training materials based on operational experience. The Action Programme provides strong leadership in promoting the essential drugs concept as a technically sound and realistic approach to rationalising drug supply systems and to making drugs accessible to the whole population. It will be important to maintain its coordinating and advocacy role, globally, at regional and country levels, at a time when many new actors are entering the pharmaceutical sector.

Photo: WHO

Delegates at the Assembly took part in lively discussions on pharmaceutical issues

In a lively and frank debate delegates focused strongly on issues related to drug pricing, access to market intelligence, quality control, drug donations and the impact of the GATT agreement on the pharmaceutical sector. Many of the concerns expressed were reflected in a resolution on the revised drug strategy (see highlights below), adopted by the Assembly.

Revised Drug Strategy

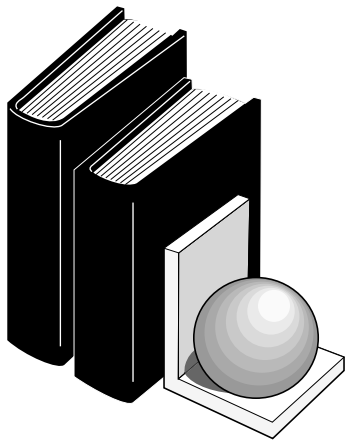
The resolution urges Member States to:

- reaffirm their commitment to develop and implement national drug policies to ensure equitable access to essential drugs;
- increase efforts to promote the rational use of drugs through the intensification of training and education of health workers and the public;
- enhance drug regulatory mechanisms for the monitoring and control of efficacy, quality and safety;
- establish and strengthen, as appropriate, programmes for the monitoring of safety and efficacy of marketed drugs;
- control unethical marketing of drugs;
- eliminate inappropriate donations of drugs, as recommended by the interagency *Guidelines for Drug Donations*, issued by WHO in May 1996;
- involve health workers, consumers, academic institutions or individuals, industry, and others concerned, in open intersectoral negotiation to develop, implement and monitor these activities, in order to improve access to and use of drugs;
- evaluate progress regularly, making use of indicators developed by WHO or other suitable mechanisms.

It requests the Director-General to:

- support Member States in their efforts to articulate the various elements of a national drug policy, improve access to essential drugs, and ensure the rational use of drugs;
- encourage Member States, as far as possible, to establish a system for the coordination and harmonisation of their national strategies;
- develop a clear strategy for review and assessment of the effectiveness of the WHO Ethical Criteria for Medicinal Drug Promotion;
- promote vigorously the use of the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce;
- disseminate the interagency *Guidelines for Drug Donations* issued by WHO in May 1996 and encourage, in collaboration with all interested parties, its use and review after one year;
- strengthen market intelligence, review in collaboration with interested parties, information on prices and sources of information on prices of essential drugs and raw materials of good quality, which meet requirements of internationally recognised pharmacopoeias or equivalent regulatory standards, and provide this information to Member States;
- continue the development, harmonisation and promotion of standards to enhance drug regulatory and quality control mechanisms;
- continue the development and dissemination of information on pharmaceutical products thereby assuring the safe, effective and rational use of drugs;
- encourage the promotion of research and the development of drugs for rare and tropical diseases;
- report on the impact of the work of the World Trade Organization with respect to national drug policies and essential drugs and make recommendations for collaboration between the World Trade Organization and WHO, as appropriate;
- report to the 51st World Health Assembly on progress achieved and problems encountered in the implementation of WHO's revised drug strategy, with recommendations for action. ❑

PUBLISHED LATELY



Important

The Action Programme on Essential Drugs cannot supply the publications reviewed on these pages.

Please write to the address given at the end of each item.

Drugs used in Sexually Transmitted Diseases and HIV Infection, WHO Model Prescribing Information Series, 1995, 97 p.

The dramatic rise in the incidence of sexually transmitted diseases that has been occurring globally for several decades has not yet been stemmed. Several million new cases are treated each year, with serious economic and social consequences as well as health implications. Directly or indirectly, these diseases are responsible for many deaths and cases of sterility, stillbirth, miscarriage, blindness, brain damage, disfigurement and cancer.

The publication provides a practical guide to the use of drugs in the management of sexually transmitted diseases and diseases associated with HIV infection. Addressed to clinicians, particularly in developing countries, the book aims to guide the selection and prescribing of drugs, in line with the latest information on efficacy, safety and costs.

Diseases covered include gonorrhoea, chlamydial infections, vaginitis, pelvic inflammatory disease, syphilis, genital herpes, chancroid, granuloma inguile, genital warts, HIV infection, AIDS and associated infections. Emphasis is placed on the importance of microbiological confirmation of both the diagnosis and the antibiotic sensitivity of the causative pathogen, even though this is still unobtainable in many settings. For each disease information includes first-choice drugs and alternatives, alerts to special precautions and what to do in case of relapse. The most extensive section is on HIV infection and AIDS. It discusses the efficacy of drugs used to treat AIDS and AIDS-related complex, and describes the typical clinical course of 13 common opportunistic and other infections, emphasising opportunities for drug management.

The second half of the book provides model prescribing information for 22 essential drugs used in the treatment of sexually transmitted diseases and diseases associated with HIV infection. Since it is often difficult to make an accurate diagnosis when a patient is first seen, even in sophisticated facilities, the book concludes with a series of flow charts for the symptomatic management of 10 commonly encountered syndromes. Their purpose is to help doctors in primary health care facilities manage patients on the basis of the epidemiological, clinical and therapeutic information available.

Available in English, (French and Spanish in preparation), from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.25/US$22.50, and in developing countries Sw.fr.17.50.

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Also in the WHO Model Prescribing Information Series:

Drugs used in Parasitic Diseases, 2nd ed., WHO Model Prescribing Information Series, 1995, 146 p.

This second edition of *Drugs used in Parasitic Diseases* reflects the changes in treatment since the publication first appeared in 1990. In particular, the sections on malaria, African trypanosomiasis, cestode infections, schistosomiasis and onchocerciasis have been extensively revised.

Available in English, (French and Spanish in preparation), from : World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.35/US$31.50, and in developing countries Sw.fr.24.50.

Bench Aids for the Diagnosis of Intestinal Parasites, WHO, 1994.

A set of nine A4 colour plates with 118 photomicrographs which illustrate the appearance and diagnostic features of all the common intestinal helminths and protozoan parasites known to infect humans. The plates are produced in a weatherproof plastic-sealed format and are intended both as a guide for laboratory and field workers in endemic countries, and as a teaching aid for students and trainees. The aim is to help the microscopist detect the presence of parasites in faeces, whether they are minute protozoan cysts or large helminth eggs, and to identify them correctly. The bench aids include laboratory instructions as well as high quality images. Relevant laboratory techniques are described on the reverse of the plates. Additional laboratory aids include dichotomous keys for the identification of amoebic trophozoites of intestinal flagellates and cysts of amoebae and flagellates.

Available in Chinese, English, French and Spanish, from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.35/US$31.50, and in developing countries Sw.fr.24.50.

Experiences with Primary Health Care in Zambia, J.M. Kassonde and J.D. Martin eds., WHO, 1994, 118 p.

This publication presents first-hand accounts of various primary health care projects implemented in Zambia over the past 15 years. By looking at the range of different approaches and analysing the reasons for their successes and failures, the book aims to provide lessons that can help other countries set realistic goals, develop well-conceived plans and avoid common errors. All the contributors – from frontline workers with non-governmental organizations to officials in the Ministry of Health – write on the basis of extensive personal experience with primary health care in Zambia. Their experiences combine to provide unique insight into the complex process of establishing a health system, based on primary health care, in a least developed country. All contributors believe that the principles of primary health care, beginning with equity, remain the only means of achieving a meaningful improvement in the health of entire populations.

Among the activities discussed are promotion of community involvement in AIDS' care and prevention, and efforts to improve the management and monitoring of primary health care. Other chapters discuss the role of traditional healers and summarise key problems encountered in most of the projects described.

Available, in English and French, from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.26/US$23.40, and in developing countries Sw.fr.18.20.

The Public and Private Circuits for the Distribution of Drugs in the Chilean Health System, WHO, Health Economics and Drugs, DAP Series No.2, WHO/DAP/96.1, 1996, 45 p.

A joint study, involving the Action Programme on Essential Drugs and UNICEF, is underway to analyse and evaluate drug management and distribution systems in some developing countries. The study aims to define the constraints on the drug distribution systems' effectiveness, in order to improve accessibility and the quality of health services generally. This report describes the Chilean drug system, particularly the public and private sectors'roles.

The publication begins with an overview of the country's economic, demographic, educational and health situation. A more detailed description of health policy and strategy follows, including public and private sector provision and financing systems. The section on pharmaceutical policy gives a breakdown of the pharmaceutical market as a whole, the generic drugs market, registration and quality control. The public and private sector distribution systems and the role of the Central Supply Agency are then discussed. The authors also assess the extent of rational use of drugs in Chile.

The publication concludes with comments on future developments in Chile's pharmaceutical sector.

Available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

Community Health Workers and Drugs, WHO/DAP/94.19, 1995, 66 p.

The publication reports on a study which analysed the role of Thai community health workers in drug distribution at the village level, particularly their impact on rational drug use. (See p. 28 for a more detailed description of the research).

Available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

Spravotchnik Vidal 1995 (The Russian Pharmaceutical Reference Book), Editions du Vidal

The first Russian version of the French pharmaceutical reference dictionary includes drug monographs on 3,500 prescription drugs. *Available, free of charge, from: AstraPharm-Servis, Pervoil Hvastov, Pereoulok, DOM 11, Office 423, Moscow, Russian Federation.*

In addition, a supplement to the French edition has been published in Vietnamese. *Available from: The Hanoi Business Centre, 51 Ly Thai Quan Hoan Kiem, Ha Noi, Viet Nam.*

How to Manage a Health Centre Store, 2nd ed., Appropriate Health Resources and Technology Action Group, 1995, 66 p.

One of the main problems faced by health centres in developing countries is how to maintain a steady and reliable supply of essential drugs, particularly when resources are scarce. Since *How to Look After a Health Centre Store* was first published in 1983, there have been many improvements in systems for managing stores and supplies. Along with a change of title, this new edition updates previous guidelines and includes examples of lists of essential drugs. Topics covered include: planning and organization, equipment, procuring and issuing supplies, and dispensing.

Available from: TALC, PO Box 49, St Albans, Herts AL1 4AX, UK. Price: £5 plus postage and packing charges (UK/surface mail add 30% of cost of book, airmail add 60% of cost of book).

Where There is No Doctor, Chinese ed., 1995

Health workers in China can now benefit from a Chinese edition of the publication, *Where There is No Doctor.* This detailed manual gives practical advice and instructions on primary health care. It provides health workers and villagers with information on the identification, diagnosis and treatment of specific illnesses, first aid, nutrition and prevention. Guidelines are given for the use of traditional and modern medicines, with risks and precautions clearly described.

The Chinese edition was translated by the Amity Foundation and published by Nanjing University. More than 90,000 copies have been printed and distributed, free of charge, in the remote rural areas of Western China.

Available from: The Amity Foundation, 17 Dajianyin Xiang, Nanjing, JS 210029, People's Republic of China.

A Book for Midwives. A Manual for Traditional Birth Attendants and Community Midwives, S. Klein, Hesperian Foundation, 1995, 519 p.

Similar in style to *Where There is No Doctor,* and also published by the Hesperian Foundation (see left), the manual is for anyone who cares for a woman during pregnancy and birth. It is particularly relevant for people who live far from maternity centres or in places where it is difficult for poor people to obtain medical care. The handbook uses simple language and hundreds of drawings, so that people with little formal education can use it.

Available from: The Hesperian Foundation, 2796 Middlefield Road, Palo Alto, California 94302, USA. Price: US$17, US$15 for orders of 12 or more copies, plus US$2 for overseas surface mail.

The Politics of Health Sector Reform in Developing Countries: Three Cases of Pharmaceutical Policy, M.R. Reich, Harvard School of Public Health, Working Paper No.10, April 1994, 35 p.

This paper discusses the political aspects of policy reform, particularly in relation to health sector reform. While many studies exist of health policies from epidemiologic and economic perspectives, few address the political aspects of health policy in developing countries. Reich provides practical advice on how to identify opportunities for change. The first section of the publication addresses the general issue of why policy reform is political. The reasons are briefly explored, to provide an approach to thinking about policy change in general, which can then be applied to the health sector. He goes on to describe three political economic models of the policy reform process: the political will, political factions and political survival models.

Reich suggests that major policy reform in the health sector is feasible at certain definable, and perhaps predictable, political moments, especially in the early period of new regimes. The most important and easily manipulated political factors seem to be: political timing, which provides opportunities for political entrepreneurs to push their ideas; and the political management of group competition, which allows leaders to control the political effects of distributional consequences and protect the regime's stability. The paper argues that for reform to succeed, policy makers must develop methods to help them understand, analyse and shape the political conditions in favour of policy reform. The method of 'political mapping' is introduced as a technique that can help policy makers in analysing and managing key political dimensions of health sector reform, and in improving the political feasibility of reform by suggesting clusters of political conditions when reform is possible.

Available from: Harvard University, Department of Population and International Health, 665 Huntingdon Avenue, Boston MA 02115, USA. Also in Health Policy, 1995; 32: 47–77.

Drug Quality Control Laboratories, WHO, Regional Office for Africa, WHO/AFR/EDV/95.1, 1995, 14 p.

Published with the support of the Action Programme on Essential Drugs, the brochure publicises the four Regional Drug Quality Control Laboratories in Africa, and provides potential users with the necessary information for their optimal use. For each laboratory, the brochure gives a brief background, indicating the equipment available, tests performed, sampling procedure and the time required to carry out particular tests. Indications are given on how to pack and dispatch samples.

Available, in English and French, from: World Health Organization, Regional Office for Africa, P.O. Box 6, Brazzaville, Congo or Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

Reference Substances and Infrared Reference Spectra for Pharmacopoeial Analysis, WHO/PHARM/95.575, 1995, 58 p.

The publication provides a list of current information, availability and sources of reference substances and infrared reference spectra for pharmacopoeial analysis. These materials are for use exclusively in analysis according to the respective pharmacopoeia. A list of addresses for the purchase of reference spectra is given. The publication will be updated on a regular basis and additional data and comments are welcomed.

Available, free of charge, from: World Health Organization, Division of Drug Management and Policies, 1211 Geneva 27, Switzerland.

Remedios Politicos para los Medicamentos, G.G. García, 1994, 292 p.

Drugs are the most commonly used therapy. Prescribing, dispensing and waiting for medication have become, for professionals and public alike, among the most frequent and "natural" of practices. However, irrational drug use is costly and dangerous and it is also a phenomenon which is rapidly spreading throughout the world. More than half the drugs currently consumed only act on the symptoms of an illness – the consequences of the disease but not its causes, the author argues. He believes that the health paradigm based on medical care and drugs is in crisis. Pharmaceutical companies are facing a more complex environment than in previous years. Drug prices are being questioned by consumers, politicians and health administrators. Concern about the adverse effects of drug use are now definitely on the agenda of the health care community.

The publication analyses these issues, with sections covering: the pharmaceutical industry; quality and consumption; and pricing, monopolies and equity. The author provides a description of the drug programme in Buenos Aires Province, Argentina. Finally, the publication looks to the future. While asserting that we may have to take some "bitter pills" before the problems connected with pharmaceuticals are resolved, the author is optimistic about the opportunities for change.

Available, in Spanish only, from: Ediciones ISALUD, Viamonte 1167 – Piso 3^0, (1053) Buenos Aires, Argentina.

Problem Drugs, A. Chetley, Health Action International, 1995, 338 p.

This is the book version of HAI's *Problem Drugs* Information Pack[1] (reviewed in EDM-16), which has been a valuable resource for health workers, pharmacists, policy makers, activists, researchers, students, journalists and many more around the world. Chetley states in clear terms what independent evaluators have said about a wide range of drugs, including antibiotics, antidiarrhoeals, analgesics, cough and cold remedies, contraceptives, and psychotropic drugs. He compares the evaluations to how the drugs are actually being used in different settings and finds serious cause for concern. Inappropriate and unnecessary use is widespread, and the point is made that 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 (misuse of antibiotics), the consequences stretch beyond a single patient or group of patients to encompass the globe.

Chetley argues that stronger controls on drug promotion are needed, and that prescribers and consumers should have greater access to independent drug information. The publication's contribution is particularly important as many products are coming off prescription, and increasingly consumers themselves are deciding which drugs to use. Chetley concludes that the evidence in *Problem Drugs* reinforces the need for governments, consumers and prescribers to be increasingly vigilant in their efforts to achieve more rational use of drugs.

Available from: Zed Books, Plybridge Distributors Ltd, Estover, Plymouth PL6 7PZ, UK. Price: £14.95. (A hardback edition is also available. Price: £39.95).

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1. As a result of funding from a German charity, Misereor, HAI-Europe is able to distribute free copies of the *Problem Drugs* Information Pack to health NGOs, health centres, medical community groups, educational establishments, and for use at seminars and workshops in developing countries. Funding covers surface mail rates, so plenty of time should be allowed if the pack is to be used as a resource for a workshop or other event. Pricing and ordering information can be provided to those in industrialised countries or the business sector of a developing country.

A limited number of information packs are available in English, Spanish, and Bengali via an organization in Bangladesh.
For further information contact: HAI-Europe, Jacob van Lennepkade 334T, 1053 NJ Amsterdam, the Netherlands.

Une politique du médicament pour l'Afrique: Constraintes et choix, C.Y. Klimek, G. Peters, 1995, 198 p.

Written by an economist and a doctor, this publication examines pharmaceutical supply problems in Africa, providing a double perspective which links economic and social aspects. The authors view economic theory as a valuable weapon in the armoury of decision makers who wish to promote access to health care as a fundamental human right.

General aspects of African drug production, marketing and consumption are addressed first, together with possibilities for improvement offered by rational use of drugs. Various characteristics of the drug industry are discussed, including the role of drug prices. This analysis leads to an examination of alternative health financing systems already operating in several countries. The authors conclude with recommendations on what they believe can and must be done to improve an often critical situation.

Available from: Editions Karthala, 22/24 boulevard Arago, 75013 Paris, France. Price: Fr.fr.150.

La rationalisation de la consultation curative par des stratégies Diagnostic-Traitement. Manuel d'emploi, (Rationalising Consultations using Diagnostic-Treatment Guidelines), Vol. 1, F. Haegeman, J.L. Ledecq, A. Wyffels, D. Kadjou, 1995, 88 p.

Guide diagnostique et thérapeutique pour le Centre de Santé, (Diagnostic and Treatment Guide for Health Centres), Vol. 2, Ministère de la Santé Publique du Cameroun, Centre d'instruction Médicale Maroua, 1995, 206 p.

Medicus Mundi Belgium has brought out a two-volume publication on rationalising medical consultations using diagnostic-treatment strategies. The first volume concerns methodology. It describes the concept, development and use of the strategies. It also explains how auxiliary staff can use them in dealing with patients, if correctly trained and supervised.

The second volume completes the method of use and is a diagnostic and therapeutic guide. The publication is intended to provide an optimal response to around 90% of health problems encountered at first-level health posts. The authors view the publication as a tool to assist diagnostic and therapeutic decisions, rather than a prescribing manual. One of the anticipated benefits is that it will facilitate the standardisation of treatment in all district health centres. In turn, this will promote equity of treatment and allow rational drug management.

Available, in French only, from: Medicus Mundi, 64 rue des Deux Eglises, 1040 Brussels, Belgium.

Pharmacy Library Pack (includes 11 publications), UK, 1995.

The high cost of drugs and supplies is one cause of the financial difficulties hospitals and health centres are experiencing. The *Pharmacy Library Pack* has therefore been produced to help managers of pharmaceutical systems to use their drugs budget cost effectively. The Pack was compiled by an expert group from four UK organizations: ECHO International Health Services, The Essential Drugs Project, The Robert Gordon University School of Pharmacy, and Teaching Aids at Low Cost (TALC).

Eleven items cover the main functions of the drug supply system: acquisition, holding, dispensing and rational and economic use. They have been chosen with the needs of hospital directors and managers, pharmacists and storekeepers in mind. The Pack contains: WHO Model List of Essential Drugs; WHO Financing Essential Drugs: Report of a WHO Workshop 1988 and Ten Questions to Ask about Revolving Drug Funds (Tropical Doctor); MSH International Drug Price Indicator Guide; CMC Guidelines for Donors and Recipients of Pharmaceutical Donations, and of Medical Equipment Donations; AHRTAG How to Manage a Health Centre Store; MSF Essential Drugs – Practical Guidelines; WHO Guidelines on Sterilisation and Disinfection Methods Effective Against HIV; British National Formulary; MSF Clinical Guidelines, Diagnostic and Treatment Manual; WHO/CDR Leaflets: Management of the Patient with Diarrhoea and Acute Respiratory Infections; and WHO/DAP Indicators: How to Investigate Drug Use in Health Facilities.

Available (as a complete pack only) from: TALC, P.O. Box 49, St Albans, Herts AL1 5TX, UK. Tel: +44 1727 853869, fax: +44 1727 846852. Price: £47 surface mail, £62 airmail.

Operational Research in the Action Programme on Essential Drugs: An Inventory, WHO/DAP/96.3, 1996, 83 p.

In this new edition, research projects have been organized according to the four technical areas of the Action Programme on Essential Drugs: policy and management; supply and logistics; rational use and quality assurance. The *Inventory* now contains more extensive summaries of research results and recommendations. An analysis of the research results of completed projects from each technical area has been added.

The *Inventory* draws on a continuously updated database, which is available to interested researchers and planners. It may be used to obtain information on specific subject areas – the use of injections in developing countries or the effectiveness of specific interventions, for example. It may also be used to gather information on a particular country or to learn about useful research methodologies.

Available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

Impact of a Short Course in Pharmacotherapy for Undergraduate Medical Students. An International Multicentre Study, WHO/DAP/95.1, 1995, 19 p.

This is a report on the impact of a short interactive training course in pharmacotherapy, using the new WHO student manual, *Guide to Good Prescribing* (see EDM-20), on the principles of rational prescribing. The impact was measured in a controlled study on 219 undergraduate medical students in Australia, India, Indonesia, Nepal, Netherlands, Nigeria and the USA.

The manual and the course presented the students with a normative model for pharmacotherapeutic reasoning. Through this they were taught to generate a "standard" pharmacotherapeutic approach to common disorders, resulting in a set of first-choice drugs called P(ersonal)-drugs. The students were then shown how to apply this set of P-drugs to specific patient problems, using a six-step model. The impact of the training course was measured by three tests, each containing open and structured questions on the drug treatment of pain, using patient examples. Tests were taken before the training, immediately after and after six months.

After the course students from the study group performed significantly better than controls in all patient problems presented. This applied to all previously discussed and new patient problems in the tests, and to all six steps of the problem-solving routine. The students not only remembered how to solve old patient problems (retention effect), but they could also apply this knowledge to new patient problems (transfer effect). Both retention and transfer effects were maintained for at least six months after the training session.

The study concludes that this approach constitutes an effective and efficient way of improving the rationality of pharmacotherapy. However, it is stressed that this can only be successful when it is accompanied by a fundamental change in the teaching methods of the trainers, away from the habit of transferring knowledge, towards real problem-based teaching of pharmacotherapy.

Available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

Making National Drug Policies a Development Priority, Development Dialogue, 1995:1, 256 p.

Ensuring that all its citizens have access to essential medicinal drugs – and are protected from useless or harmful ones – should be a high priority for any country. But national drug policies, a vital part of overall health policy, have faced strenuous opposition from powerful vested interests, and no country is immune to negative international presssure, argues this special edition of *Development Dialogue.*

The publication covers six country stories – from Norway, Sri Lanka, Bangladesh, Australia, India and Mexico – and a strategy paper on protecting and developing health and drug policies. All the contributions are written, singly or jointly, by acknowledged experts in the field. A preface to the case studies, situates the experience of individual countries in the context of initiatives taken by the Non-Aligned Movement, UNCTAD, WHO and campaigning health organizations since the l970s to promote the provision and rational use of drugs.

The six country studies, revealing the factors that have determined the relative success or failure of individual national drug policies, are a substantial resource for others attempting to devise and implement similar policies. A crucial lesson from all the case studies is that pharmaceuticals must be tackled as an integral part of the general development of a country, including health, education, access to information and regulation of the private sector.

Concerted action is urgently needed to safeguard well-functioning NDPs and improve health care and drugs provision universally. The strategy paper argues persuasively for a holistic approach. This will involve international and multinational organizations, national governments, health professionals, non-governmental organizations, the pharmaceutical industry itself and consumers.

The recommendations are not prescriptive, but clear guidelines are suggested. Priorities identified are: close analysis of the impact of trade and harmonisation initiatives on the pharmaceuticals trade and drug regulation; support for WHO's Drug Action Programme; and a wide-ranging educational campaign, targeting health professionals and consumers in particular.

Available from: The Dag Hammarskjöld Centre, Övre Slottsgatan 2, S-753 10 Uppsala, Sweden. Fax: +46 18 122072.

Selecting Medical Supplies for Basic Health Care, R. Skinner, J. Townsend, V. Wells, ECHO, 1995, 30 p.

In view of the great financial pressures experienced by health services, there is a critical need to ensure that the best and most efficient use is made of all supplies. For many years WHO's Model List of Essential Drugs has been helping countries meet their highest priority treatment needs with a well-chosen list of basic low-cost products. As yet no one had developed a satisfactory model list of essential medical supplies to complement the drugs list. With its new publication, Equipment for Charity Hospitals Overseas (ECHO) has provided a list which facilitates choice of the most appropriate supplies for basic medical care. The authors identify the essential stocks that should always be available; and give advice on priority setting for procurement and good supply management in medical stores, hospitals and clinics.

The authors stress that a model list has to be transformed into a standardised local list. They encourage the setting up of standard practice protocols, which can guide health workers into more cost effective clinical practice by specifying the appropriate medical supply items to use in diagnosis and care.

The publication will be useful for health ministries, supply organizations, health care institutions and development agencies.

Available from: ECHO International Health Services, Ullswater Crescent, Coulsdon, Surrey CR5 2HR, UK. Price: £3.

Third edition of European Pharmacopoeia

The third edition of the European Pharmacopoeia is now available. The monographs and regulatory texts it contains have mainly been drawn up by groups of experts from the public health authorities, universities and the pharmaceutical industry in the states that have signed the Convention on the Elaboration of a European Pharmacopoeia.

On 1 January 1997 the new edition will be a single reference for 25 European countries and the Commission of the European Communities.

For further information contact: European Pharmacopoiea, 226 Avenue de Colmar BP 907–F67029 Strasbourg, France. Tel: +33 88 41 20 36, fax: +33 88 41 27 71.

Deception by Design: Pharmaceutical Promotion in the Third World, J. Lexchin, 1995, 91 p.

The book focuses on drug promotion in developing countries, where, it states, companies are much less restrained and factual in their advertising than in industrialised ones. The author argues that promotional material often extends indications for drugs into areas for which there is no scientific evidence, with side effects and contraindications minimised or even ignored.

Lexchin believes that among the main problems are too many detailers, with too little training and knowledge, giving too many "free" samples and "gifts" to doctors. He raises the issue of bogus clinical trials and biased conferences which drug companies finance but which are then claimed to be "independent". Another major concern is what Lexchin calls the "war" on generics. He wants consumers to be aware that for nearly all the most important medicines there are low cost generic equivalents, identical in composition and equal in quality to the brand name products so heavily promoted by drug companies.

The book argues that while problems associated with drug promotion in developing countries may be serious, it is possible to take concrete steps to deal with them. Already a variety of consumer and professional groups, nongovernmental organizations and governments have started the process. Lexchin makes a number of recommendations to expedite change. Among these he calls for an end to self-regulation by the pharmaceutical industry and the introduction of rigorously enforced laws "banning irrational, useless and dangerous" products. In addition to removing these products from the market in developing countries, developed countries must accept responsibility for controlling drug exports, Lexchin states. He calls for exporting countries to develop policies that prohibit the export of pharmaceuticals which have been banned, withdrawn, restricted or deregistered in their country of origin.

The author advocates compulsory generic prescribing and an end to advertising of prescription drugs direct to the public. He also urges multinationals to provide essentially the same information to all physicians wherever they market their drugs. Lexchin wants marketing codes to be strengthened and enforced, and calls for improved application and monitoring of WHO's Ethical Criteria for Medicinal Drug Promotion.

Available from: Consumers International, Regional Office for Asia and the Pacific, PO Box 1045, 10830 Penang, Malaysia. Price: US$15 (seamail). A special discount price is available for groups in developing countries, HAI members and large orders.

Catalogo Nacional Farma, 11 ed., Ministerio de Salud, Republica de Colombia, National Pharmaceutical Catalogue, 1996, 146 p.

Colombia's Ministry of Health is committed to promoting rational drug use and to encourage this it produces a National Pharmaceutical Catalogue. The publication contains an alphabetical list of drugs available on the Colombian market and their prices. Products are under generic name and comparative prices of brand name drugs are given. Essential drugs are highlighted in green. The catalogue not only helps doctors and dentists to select drugs on the grounds of quality and cost, it also makes patients more aware of pharmaceutical pricing. Updated every three months, the publication has been the subject of a major national promotional campaign. It is obligatory for all public and private sector pharmacies to put up posters informing their customers that the catalogue exists, and urging them to request a copy.

Available from: Ministerio de Salud, Carrera 13 Nº 32–76, Santa Fé de Bogotá, Colombia.

Health Financing Reform in Kenya: The Fall and Rise of Cost Sharing, 1989–94, D.H. Collins, J.D. Quick, S.N. Musau, D.L. Kraushaar, 1996, 128 p.

Experience with cost sharing in Africa is still growing. The importance of health financing issues, and the difficulties of designing and implementing cost sharing programmes, make the interchange of experience among countries a vital part of the successful development of health financing strategies.

Initial efforts to introduce cost sharing in Kenya in 1989 failed because of flaws in design and implementation. The programme almost collapsed in the face of widespread public and political rejection. Between 1991 and 1994, the programme was redesigned and reimplemented. *Health Financing Reform in Kenya: The Fall and Rise of Cost Sharing, 1989–94* describes the implementation of the cost sharing programme and the lessons learned from it.

This monograph will help policy makers, planners and implementers to understand some of the requirements for the successful introduction of cost sharing.

Available, free of charge, from: Director, Health Financing Programme, Management Sciences for Health, 165 Allandale Road, Boston, MA 02130, USA.

Cancer Pain Relief, with a Guide to Opioid Availability, 2nd ed., WHO, 1996, 63 p.

The thoroughly revised and updated edition further refines WHO's simple yet highly effective method for the relief of cancer pain. WHO advocates the use of a small number of relatively inexpensive drugs, including morphine, to alleviate suffering.

The book begins with a practical guide to the relief of cancer pain, concentrating on drug treatment as the mainstay of pain management. A nine-step procedure for the evaluation of pain is provided. The section on the principles of treatment includes a tabular list of 11 basic drugs and 18 alternatives. The most extensive section sets out detailed guidelines for drug selection and prescribing. Readers are reminded that psychological dependence does not occur in cancer patients.

A new section has been added, describing the international system by which morphine and other opioids are made available to patients who need them. This part of the publication will be of interest not only to health care workers, but also to drug regulators responsible for implementing the Single Convention on Narcotic Drugs at national level.

Available in English, (French and Spanish in preparation), from : World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.17/US$15.30, and in developing countries Sw.fr.11.90.

Working Group on Drug Quality Control in Africa. Report of a Meeting, Brazzaville, 3–8 October 1994, WHO, Regional Office for Africa, WHO/AFR/EDV/95.2, 1995, 37 p.

This is a report of a working group meeting on drug quality control in Africa. Representatives of nine countries discussed how, through training, information, technical and financial support, quality control in the Africa Region can be improved. The report focuses on four main topics: the publication of a brochure on the four Regional Drug Quality Control Laboratories; the conditions for WHO financial support to analyse 400 drug samples; training for the laboratories' technicians; and the conclusions of the assessment of the use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce, with a view to reinforcing drug registration and controlling drug importation in Africa.

The document concludes with implementation plans drawn up by participants, followed by annexes which include copies of a Certificate of a Pharmaceutical Product, a Statement of Licensing Status of Pharmaceutical Product(s), a Manufacturers/Official Batch Certificate of a Pharmaceutical Product, and a list of drugs to be regularly controlled.

Available, free of charge, in English and French, from: World Health Organization, Regional Office for Africa, P.O. Box 6, Brazzaville, Congo or Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

Update on new formularies, treatment guidelines, essential drugs lists, drug bulletins and newsletters

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The Action Programme on Essential Drugs produces a global index of drug formularies, therapeutic guides and essential drugs lists, which is available free of charge. (Please note that we are unable to supply copies of the publications themselves. Requests should be addressed direct to the countries concerned). Some recent additions are:

- Argentina's *Formulario Terapéutico Nacional*, 1995. Confederación Médica de la República Argentina. A national formulary.
- Belarus' *Essential Drugs List*, 1995. Ministry of Health. Includes 250 drugs. In Russian.
- Chile's *Formulario Nacional de Medicamentos*. 1996. Ministerio de Salud. A national formulary which includes 304 drugs.
- Côte d'Ivoire's *Liste des Médicaments essentiels*, 1995. Ministère de la Santé publique et des Affaires sociales. Full list contains 281 drugs in 18 therapeutic groups, also includes sub lists for 5 levels of health care.
- Georgia's *Georgian Pharmacological Formulary*, 1995. Ministry of Health. Includes the essential drugs list.
- India. Tamil Nadu State Government Health Service's *List of Essential Drugs and Surgical Items 1996–97*, 1996. Tamil Nadu Medical Services Corporation Limited. Generic drugs listed in 25 therapeutic groups.
- Indonesia's *Kompendia Obat Bebas*, 1996. Ministry of Health and Food and Drug Administration. Over-the-counter drugs formulary for the public.
- Maldives' *List of Essential and Approved Drugs*, 1995. Ministry of Health and Welfare. 532 drugs listed by generic name with conditions of sale (e.g. prescription/non prescription) included.
- Poland's *Przewodnik farmakoterapii*, 1995. Polish Pharmacological Society and the National Physicians Institute. A national formulary.
- Rwanda's *Liste des Médicaments essentiels par Niveau de Soins*, 1995. Ministère de la Santé, Direction de la Pharmacie. 205 drugs listed by generic name in 26 therapeutic groups, for 3 levels of use.
- Singapore's *Standard Drugs Formulary*, 1995. Ministry of Health. Drugs in 20 therapeutic groups. Includes prescribing guidelines.
- South Africa's *Standard Treatment Guidelines and Essential Drugs List for Primary Health Care*, 1996. The Department of National Health. Essential drugs listed in 24 therapeutic groups.
- Turkey's *Essential Drugs List*, 1995. Turkish Medical Association. List containing 382 generic drugs.

Drug bulletins and newsletters

- Eritrea's *Drug Bulletin*. The first issue of Eritrea's Drug Bulletin was launched in August 1995. Published bimonthly by the Department of Pharmaceutical Services in the Ministry of Health, it aims to promote rational drug use among health workers by providing reliable information on drugs and therapeutics.
- Zanzibar's *Pharmaceutical Newsletter*. Published by Zanzibar Drug Information Centre. A quarterly newsletter which covers drug policy, legislation, rational use, alerts and adverse drug reactions, prescriber and patient information, and traditional medicine.

RESEARCH

Where Thai villagers get their drugs

Luechai Sringernyuang, Thavitong Hongvivatana and Penchan Pradabmuk*

DRUGS, specifically essential drugs, are a fundamental element of primary health care and, according to the Alma Ata Declaration, should be available at all levels of primary health care at the lowest possible cost. To attain that goal, many countries provide essential drugs through community health workers, another cornerstone of primary health care. This method of supply not only makes drugs more accessible to the people who need them, but also helps strengthen the community health workers' role and status.

In Thailand, the Primary Health Care Programme was launched nationally in 1978. Two types of community health worker were trained countrywide. One, called the village health volunteer (VHV) undertook curative and preventive tasks, and the second, the village health communicator (VHC), had a narrower range of duties, such as disseminating information on health problems affecting the village. One of the community health workers' important functions was to provide essential drugs through the village drug fund (VDF), a community-based organization devised and promoted by the Ministry of Public Health. The main objectives of such funds were to: be a distribution outlet for essential, cheap and good quality drugs; enhance health workers' performance; encourage community participation; raise funds for other community development activities; and contribute to the protection of consumer rights. By 1991, 35,819 such funds had been set up throughout the country. However, there have been many obstacles to the success of community health workers' drug provision role. The national primary health care programme has been faced with the problem of a high drop out rate among VHCs and difficulties in retaining the active VHVs. In addition, community health workers have tried to establish their drug distribution role in an environment where drugs are plentiful and available from a number of sources.

A study was undertaken in Thailand as part of a research project, "Intercountry Study on Implications of Community Health Workers distributing Drugs". The aim was to analyse the role of community health workers in drug distribution at the village level, in order to determine the impact on improving drug use by consumers and on achieving the full range of community health workers' activities. Other available drug sources at the village level were also examined and quantified. Both quantitative and qualitative methods of data collection were used, including: a mailed questionnaire survey; a rapid appraisal survey of drug sources in the village; field-visits; and village case studies. Research was undertaken in eight provinces, chosen to be as culturally and socioeconomically representative of their region as possible.

An abundance of drugs and sources

The difficulties experienced by community health workers in providing drugs through village drug funds were reflected in the research results. Functioning drug funds were found in roughly half the villages. Most were single units, not combined with other activities in a cooperative or merged with a grocery. Groceries, in fact, were the most common source of drugs, and there were an average of four grocery shops per village. Drug pedlars visited almost all villages, selling drugs ranging from over-the-counter and prescription drugs to herbs and "Ya-Chud" (mixed bags containing various drugs, including prescription drugs). Clinics run privately by government health centre staff and hospital nurses in their spare time were an important source of injectables. Injectionists (paid professionals who were mostly former army orderlies with basic medical knowledge from their military service or amateurs who were villagers who may have learnt some skills from professionals) were a source of antibiotics and intravenous solutions. This abundance and easy availability of drugs in the villages created an extremely unfavourable environment to improve drug use by consumers.

Over-the-counter drugs, prescription drugs and traditional medicines were available (an average of 42 branded products) in every village. Eighty-two per cent were modern pharmaceuticals, 20% of which were prescription only drugs. Antibiotics formed the largest proportion of the prescription drugs with 54%, followed by anti-inflammatory drugs (11%), antidiarrhoeals (11%) and "Ya-Chud" (10%).

At the village level, no marked provincial or regional differences in drug sources were found. The situation was quite similar in the majority of villages: a wide range of drugs from various sources. However, village size (measured by the number of households) was a decisive differentiating factor. The bigger villages, which had more drug outlets – specifically a large number of groceries – had a wider range of drugs than the smaller ones. This reflects the current national situation, in which drug sources respond to demand, and restrictions on drug sales are rarely implemented. The presence of other types of drug sources, such as private clinics and drug pedlars, also reflects the demand side. Private clinics with health centre staff and district hospital nurses are always located in the well populated villages. In this study injectionists appeared to be present in areas that are peripheral and relatively backward in socioeconomic terms.

Village drug funds: a limited role

Three major forms of village drug fund were found: the single VDF (the majority), the VDF merged with a grocery (VDF/grocery) and community centres for primary health care. Introduced in 1992, the centres provide preventive and curative care, and coordinate all village health development activities. In many villages with a community centre defunct VDFs have been reopened or existing ones merged as part of the centre.

Research results showed that at the single VDF a very limited range of drugs was available, and this was also the case at community centres for primary health care (although few data were available due to the centres' recent introduction). In both cases the drugs were mostly over-the-counter products from the Government Pharmaceutical Organization. Because the single VDF usually kept the smallest range of drugs of all available village drug outlets, it had a very low sales volume and was, consequently, difficult to sustain. Many still considered to be functioning had a very "sleepy" existence. As a result of these limitations single village drug funds played a very limited role in household drug use. The household drug use survey in 10 villages with such a fund investigated cases of diarrhoea, cold and cough, fever and headache, stomach-ache, and muscle pain (tracer illnesses). A total of 644 episodes were recorded.

Findings showed that in the majority (45%) of cases, the medicines used were purchased from grocery shops. Drugs from VDFs were acquired in only 12% of episodes and in a very selective manner: more frequently for cough and cold, fever and headache but much less frequently for diarrhoea, stomach-ache and muscle pain. In contrast, VDF/groceries were run commercially and responded to community demand for a wide variety of drugs. Their stock included about 20% prescription drugs. Hence, the single VDF lost its role as provider of essential drugs to the villagers. Health centres, district hospitals and private clinics were relatively important sources of drugs for episodes of severe diarrhoea and cough and cold. Drugstores in towns, traditional practitioners and injectionists were seldom visited for these kinds of common illnesses. However, in cases of serious and chronic work-related complaints, injectionists and private clinics were frequently used as well as groceries.

The next steps

Generally, it can be concluded that community health workers and single VDFs play an extremely limited role in the provision of drugs in Thai villages, and their contribution towards appropriate use of drugs by consumers is very small.

On the basis of these findings, the research team made three main recommendations to the Thai Ministry of Public Health. First, Thailand should immediately implement a policy that directly addresses promotion of rational drug use by consumers at all levels. National drug policy must emphasise the appropriate use of drugs in self-medication. Enforcement of regulations and strict control of the distribution of prescription drugs in particular, are needed. Accompanying measures should include the promotion of essential drugs, especially in the private sector, a reduction in the range of available non essential drugs, and regulation and control of all forms of drug advertising. Second, a public education campaign on appropriate use of drugs must be instigated, using a participatory approach. It should address the reasons why people use drugs inappropriately, and inform consumers of potential side effects and contraindications of drugs. Third, because the prevailing socioeconomic conditions make the present village community health worker scheme difficult to sustain, the Government should study ways to develop primary health care which is better adjusted to the needs and health requirements of village populations.

An additional recommendation, to health NGOs, is that they should form a decentralised consumer organization to monitor drug provision and consumption at the village level. ❑

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Ed. note: The fifteen-year experience with Thailand's village drug funds, the early history of which is described in other WHO documents[1], demonstrates that community drug schemes can be established on a large scale, provided there is adequate start-up funding, active community participation, a reliable source of essential drugs and trained village health workers. At the same time, Thailand has undergone tremendous economic growth and social change during this period. When such dramatic change occurs, community needs also change. Thus, programmes to promote access to essential drugs and rational use of drugs must also evolve if they are to meet the changing needs of communities. Ed.

Reference

1. Review of the drug programme in Thailand. Report of a WHO Mission. Geneva: World Health Organization, 1986. DAP/88.5

Photo: A. Reeler

A village health volunteer at a village drug fund in Udon Thani Province