



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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EDITORIAL

Improving drug use

WE used to think that irrational drug use was only based on a lack of information and training. Now we are wiser. We understand that although good teaching and access to scientifically validated information is a prerequisite for appropriate drug use, many other factors are involved. Drug use is impacted by a complex web of knowledge, attitudes, practices and influences that goes far beyond the usual biomedical model, and that can vary widely between countries, professional groups and the general public.

This issue of the EDM reports on an important international conference which for the first time brought together researchers, policy makers and health managers from all over the world to discuss and define the "state of the art" in improving the use of medicines.

Complex problems demand complex strategies. Different disciplines have important and equally valid contributions to make in understanding patterns of drug use and misuse. For this reason a multidisciplinary approach was at the heart of the conference. Paradigm papers which examined the constructs and tenets of different models, such as those of biomedicine, economics or politics, illustrated the need for a multidisciplinary approach. The conference identified many key lessons in the areas of drug policy, drug financing, hospital and primary health care levels, and patient and community education.

In developing and implementing a drug policy, critical factors are the political will, stability of government, involvement of stakeholders and appropriate timing. A strong consumer movement and supportive media are also key elements. Careful monitoring and evaluation are needed so that unintended consequences or constraints can be quickly identified, and successful strategies reinforced. Widescale use of WHO's national drug policy indicators can contribute here. Better collaboration between policy makers, researchers and stakeholders is needed to strengthen the link between theory and practice. And one ex-minister of health urged scientists to learn to speak the language of politicians. Probably all of us need to develop a working knowledge of each other's professional "languages".

Drug financing interventions require clear objectives and good baseline data before user fees or other mechanisms are

introduced so that their impact can be measured and understood. It is known that patient attendance depends on the level and type of fee and the quality of care, that high fees tend to be inequitable and that a fee per visit tends to encourage overuse of drugs.

At the hospital level in developing countries very few studies have been carried out. Yet there is a strong case to make for these since hospitals often account for a large proportion of public spending on drugs, influence national prescribing patterns, and hold accessible data. The principle of evidence-based medicine, which is gaining considerable acceptance in academic hospitals, needs to be more widely extended.

At the primary care level there is compelling evidence that the simple dissemination of information, such as treatment guidelines, is not sufficient to cause measurable improvements in behaviour. However, guidelines developed with user input and accompanied by training, audit and feedback, do result in improved drug use, each additional measure adding to the effect. Access to comparative, independent drug information is essential for such work.

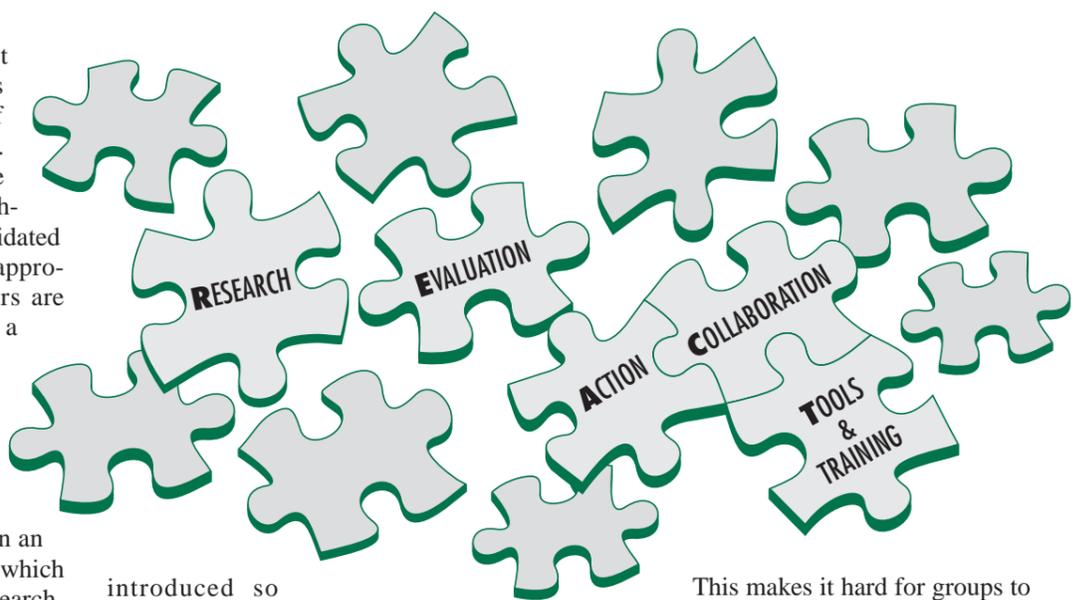
We also have evidence that knowledge and understanding improves medicine use by patients during short-term treatment regimes. But different types of illness and therapies require different strategies to ensure appropriate use. Patients need information that is understandable so that they know what drugs they are taking, for what reason and how. And prescribers and dispensers need training to improve the way in which they communicate with patients.

According to a recent DAP global survey, little of the work in consumer drug education is being written up and reported.

This makes it hard for groups to learn from each other, to improve planning and to gain sustained support. Effective strategies are needed to promote empowered consumers and to evaluate consumer-based interventions. Consumer education initiatives will only work if they are developed in cooperation with those involved and are relevant to their needs and beliefs. We also need to recognise that behaviour change can be a difficult and long process that may move along a continuum of awareness raising, knowledge acquisition, belief in ability to act and finally change in practice.

After synthesising the conclusions of this rich body of work, where do we go from here? More research is needed, building on the insights and priorities identified by the conference. In particular, new ways of evaluating and understanding complex processes need to be developed. Many interventions to improve drug use have never been evaluated. Encouraging researchers and policy makers to evaluate and report their activities is essential.

Scientific research and evidence are vital, but alone they are not sufficient to achieve change. If we wish not just to advance knowledge but to improve drug use and health we need to move from research into policy and implementation, from study into action. The essential drugs concept is a global concept. It is evidence-based, cost-effective, tried and tested. However, it has not been universally adopted because its implications are political and the area of drug policy is a controversial one with conflicting interests. The conference stressed that besides research data, ideals, commitment and political will are needed to translate evidence into action. □



SUPPLY

Educating the donor

Improving drug donations from Western Europe

➤ MARK RAJMAKERS
AND ALBERT PETERSEN*

THE interagency *Guidelines for Drug Donations*, issued by WHO in May 1996, have triggered a number of actions aimed at improving the quality of drug donations from Western Europe. Both governmental agencies and nongovernmental organizations (NGOs) are playing important roles in promoting and translating the guidelines, and in adapting them to national circumstances.

In general all the principles set out in the interagency guidelines are reflected in these national versions. However, some countries have chosen to emphasise specific aspects because of their national relevance. In some instances, the

guidelines have also been used to point out gaps in national drug policy, although no legislation on donations has yet been enacted in Western Europe. Some of the ways in which the guidelines are being promoted, used and adapted are described below.

RETURNED DRUGS: A MAJOR CAUSE OF INAPPROPRIATE DRUG DONATIONS

The collection of returned drugs is a major cause of inappropriate drug donations from Western Europe. Most professional aid organizations subscribe to the interagency guidelines. The problem lies mainly with small groups who

have little awareness of the possible negative consequences of drug donations. In addition some inappropriate industry donations need improvement.

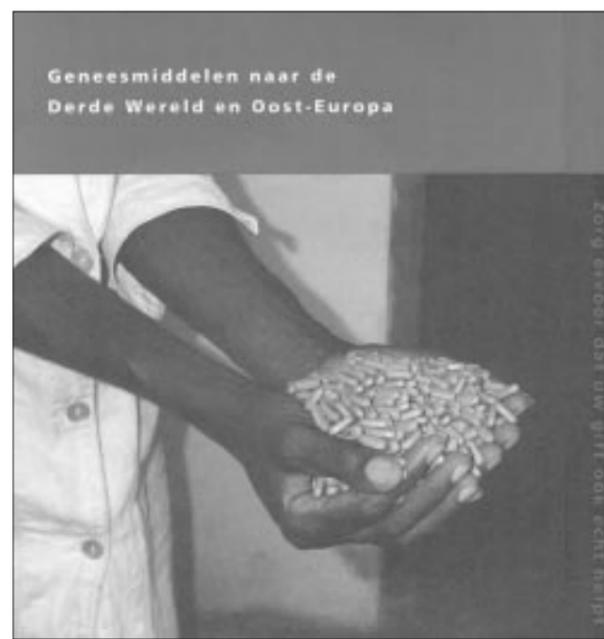
To combat the problem of donating returned drugs, awareness-raising campaigns targeting consumers and donor organizations have been carried out in a number of countries, including the Netherlands and Germany.

Dutch NGOs join forces

In the Netherlands, almost all returned drugs given as donations are collected by pharmacies. And a 1994 survey by the University of Utrecht revealed that this involved at least 60% of pharmacists¹. A majority of Dutch pharmacists gave drugs to charity organizations for donation purposes, often with limited knowledge of the situation at the recipients' end. In 1995 a group of 10 Dutch NGOs formed a "Committee on Drug Donations". With government support, they launched a nationwide campaign to improve the quality of national drug donations. This included:

- ◆ the distribution of 35,000 copies of a leaflet to inform the public about drug donations, which was distributed through pharmacies and general practitioners;
- ◆ discussions with pharmacists at FarmaVisie, the national professional fair;
- ◆ the launch of an information centre on drug donations at the Royal Dutch Pharmaceutical Association in The Hague, by the Dutch Minister of Health.

Results from the campaign are promising. Research at the beginning of 1997 revealed that only 25% of pharmacists now provide aid organizations with returned drugs, and attitudes to drug donations indicate a shift towards following the guidelines. At the end of 1996 the Dutch Health Inspectorate sent a letter to all pharmacists and general physicians to officially disapprove of using returned drugs for donation purposes. A seminar, structured around the interagency guidelines, was organized on pharmaceutical aid to Romania, a country where major problems had been identified with drug donations².



As part of the Dutch campaign 35,000 copies of this folder, *Drugs to the Third World and Eastern Europe*, were distributed to the public via pharmacies in the Netherlands

Use of the Guidelines in some Western European Countries



Germany

DIFÄM (Deutsches Institut für Ärztliche Mission, German Institute for Medical Missions) and Misereor, a German development funding organization, produced an adaptation of the guidelines in colloquial German, which was distributed to 3,000 individuals and donor NGOs in Germany, Switzerland and Austria.

Italy

The Directorate General for Development Cooperation of the Ministry of Foreign Affairs translated the guidelines and distributed several thousand copies to NGOs and local government agencies involved in humanitarian aid.

Norway

National guidelines were developed and issued by the Board of Health in June 1997 and distributed to all pharmacies, professional organizations, doctors, major NGOs, wholesalers, and relevant ministries. The Norwegian guidelines also include dispensing materials, pharmacist approval, an obligatory export permit, and that the recipient should be the national health authority (see page 5).

The Netherlands

Dutch guidelines have been published by the Committee on Drug Donations (Werkgroep Geneesmiddelen donaties) in cooperation with government ministries. The document emphasises the double standard of sending returned drugs as donations, since redistribution of returned prescription drugs is forbidden in the Netherlands. It also points out the legal need for a wholesale licence to store and transport drugs.

United Kingdom

The interagency guidelines have been widely distributed within the Ministry for International Development (former Overseas Development Agency) and by British NGOs such as ECHO (a non profit supplier of essential drugs to developing countries), and the Essential Drugs Project, which focuses on information to developing countries.

Spain

Prosalus, a health development NGO, is planning to adapt the interagency guidelines at the beginning of 1998 and to distribute copies to all Spanish NGOs, relevant health organizations and pharmacists' associations.

Note: Information on national activities was provided by members of HAI's Working Group on Drug Donations. Readers with additional information should contact the Group Secretariat (see end).

and medical students at German universities. The media too have been successfully involved in the national campaign. More than 30 articles on the issue appeared in newsletters and pharmaceutical and medical journals during 1996.

LESSONS LEARNT

It takes time to change individual and organizational practice. Donation practices related to returned drugs are particularly difficult to change for a number of reasons. Such activities are longstanding, and generally motivated by a real desire to help from organizations and individuals with high ideals. Much of the work is carried out on a volunteer basis. Moreover, many groups and consumers consider it a waste to throw things away which they still consider "good". Campaigns to change donation perceptions and practices in Western Europe have led to some valuable lessons which can be used by others working in this area.

Bring the issues to life...

The current level of knowledge about the essential drugs concept, rational drug use, and the pharmaceutical situation in the recipient country among humanitarian aid donors is often very low. Much needs to be done to explain the negative consequences of certain donation practices. Examples of bad donations, such as those published in previous issues of the *Essential Drugs Monitor* and other international publications, certainly help but may not always be identified with. Working with national media and local examples can increase identification. Inappropriate drug donations are a highly sensitive media issue, and experience in Germany and the Netherlands has shown that responsible journalists can highlight problems and support educational efforts.

Identify and support key partners...

Identifying and drawing on key people and organizations, who have already strengthened donation practice and can speak from experience, is an effective strategy. Such organizations can increase their impact through effective networking and support in joint strategy development.

Offer alternatives...

It is important to adapt the message to the target audience and be as concrete as possible. Proposing alternative action is an essential part of this message. The interagency guidelines suggest useful alternatives for donors seeking other ways to help. Since collecting material for donation is a traditional part of many aid organizations' work, another alternative could be to offer medical equipment instead of drugs. In this case clear guidelines are essential to ensure that equipment is really needed and useful,



Dr Els Borts-Eilers (centre), Minister of Welfare, Health and Sports of the Netherlands, examines a box of donated drugs at Farma Visie 1996, the national pharmaceutical trade fair

Photo: B. Gebuys

and to prevent many of the problems which have arisen with drug donations⁵.

Secure government support...

Some European governments provide funding for drug donation education campaigns. A number have clarified their national drug policy on donations by translating and distributing the interagency guidelines. But overall, awareness about the possible consequences and extent of national drug donations is still not high in most European governments. At present, the European Commission has no specific directives for drug donations⁶. Groups working to improve the quality of drug donations should therefore advocate the use of the guidelines for drug donations in the policy of government institutions, such as aid departments and the ministry of health. Government support is essential to an effective campaign.

Monitor developments...

A significant number of donor organizations do not accept the interagency guidelines. They still believe that it is better to send something than nothing

and that the quality of returned drug donations can be guaranteed. Experience from both donors and recipients needs to be shared so that problems are openly identified and articulated, and quality improved⁸. To do this there is a fundamental need for systematic surveillance of drug donations worldwide.

CONCLUSION

Progress is apparent. Awareness of the need for drug donation guidelines has increased in some European countries. The interagency guidelines have been or are being translated or adapted and widely distributed in several donor countries. In some countries this has also been backed by education and awareness-raising activities.

The guidelines and other related work have contributed to some change in practice and certainly to stimulating keen discussion of the issues. However, widespread changes in donation practice can

probably only be effected in the long-term. And this will require sustained information, education and support, together with monitoring.

We believe that as a first step governments need to spell out clearly their drug donation policy and to identify gaps in legislation. Support to, or organization of, education campaigns on this issue is the next step. This has to be accompanied by strengthened communication between donor and recipient organizations and countries. Recipients must play the major role in defining and specifying the drug needs. They can also play an important role in awareness-raising activities by working together with organizations that are trying to strengthen drug donation practice through monitoring and other activities. □

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The Committee on Drug Donations' stand at Farma Visie 1996

Credit: Werkgroep Geneesmiddelen donaties

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Notes

1. Blom ATG, de Bruijn JCMJ, van de Vaart FJ: Wat doet de consument met overgebleven receptgeneesmiddelen [What does the consumer do with left-over prescribed medicines]? *Pharmaceutisch Weekblad* 1996; 131 (4): 102-107.
2. Wemos. Pharmaceutical aid to Romania. Exchange of knowledge and experience. A report on a seminar for NGOs in Utrecht, the Netherlands, November 1996.
3. DIFAM: Leitfaden: sammeln für die Dritte Welt [Guidelines: collecting for the Third World]. Tübingen: 1996.
4. DIFAM. Supply of pharmaceuticals to the Third World. A position paper of the Church and the pharmaceutical industry.
5. CMC - Churches' Action for Health, World Council of Churches: Guidelines on equipment donations. A guide for those accepting and making donations.
6. Directives 9/689/EEC, 84/631/EEC, and 92/25/EEC of the European Commission. Returned drugs can be considered as toxic waste. For transporting drugs, a wholesale licence is required.

§ Editor's note: The WHO Action Programme survey reported on page 5 is a step in this direction.



Photo: E. Schoulen

Different bottles in a donation of returned medicines for Rwanda. No information leaflets were sent



SUPPLY

Drug donation guidelines: gathering momentum

THE interagency *Guidelines on Drug Donations*¹ (see EDM-21) have already begun to achieve one of their stated aims – to serve as a basis for governments and organizations dealing with drug donations to produce their own documents. Zimbabwe and Australia are among the first countries to publish national guidelines, and they do so from differing perspectives – Zimbabwe as a recipient and Australia as a donor country.

ZIMBABWE

Introducing the *Guidelines for Drug Donations for The Republic of Zimbabwe*, Minister of Health and Child Welfare, Dr Timothy Stamps, states “On many occasions Zimbabwe has had to meet considerable unexpected expenditure to process donations that had not been properly planned”. The *Guidelines* will help “avoid the occasional unpleasant decisions I have in the past had to make, choosing either to accept the donation and destroy it, or refuse and give offence to a willing supporter of our health care system”. Stressing that appropriate donations can provide valued assistance, Dr Stamps asked all involved to ensure that the *Guidelines* are followed precisely.

The Zimbabwe *Guidelines* closely mirror the interagency ones, and have the following main provisions:

Selection of drugs

All donated drugs must be based on an expressed need, be relevant to the disease pattern in Zimbabwe and receive prior clearance, except in acute emergencies. All drugs must be on the country's most recent essential drugs list, with the dosage form, strength and formulation similar to those commonly used in Zimbabwe.

Quality assurance and shelf-life

All donated drugs must originate from a reliable source and comply with quality standards in both the donor country and Zimbabwe. The WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce should be used, and relevant batch certificates included. The Zimbabwe Medicines Control Authority must register all the drugs, or in exceptional cases where this is not possible must clear the drugs before they can be released for distribution.

Presentation, packing and labelling

The labelling requirements are largely the same as those in the interagency document, but Zimbabwe asks for the date of manufacture of the donated drugs and that this and the expiry date are given “as clear

dates not codes”. Also all drugs should be accompanied by prescriber information in English.

As far as possible, donated drugs should be sent in large quantity units and hospital packs as used in the Republic of Zimbabwe, (donors are referred to the Government Medical Stores Catalogue). Donations of paediatric syrups and mixtures are discouraged. The detailed packing list is the same as in the interagency *Guidelines*, except that the Zimbabwe publication states that different drugs should not be packed together in one carton.

The Secretary for Health at the Ministry of Health and Child Welfare and the Government Medical Stores should be informed of all drug donations that are being considered, prepared or actually underway. “The information should extend to delivery dates, possible delays, port of entry, method of transport, etc”.

The declared value to the Republic of Zimbabwe of a drug donation should be based upon the wholesale world market price for its generic equivalent. As with the original *Guidelines*, Zimbabwe asks that all international and local transport costs, warehousing, port clearance and appropriate storage and handling should be paid by the donor, unless specifically agreed in advance. In addition, it requests that donors pay for quality testing and that the “cost of disposing of a drug donation adjudged to be unsuitable should be borne by the donor”.

AUSTRALIA: A DONOR COUNTRY PERSPECTIVE

The introduction to the *Australian Guidelines for Drug Donations to Developing Countries* states clearly why the publication is needed. “The contribution of medicines in the form of donations to developing countries or in disaster situations is often viewed by communities in developed countries, such as Australia, as a useful way to provide much needed pharmaceutical supplies...As the lack of medicines is often presented as a pressing problem, an immediate donation of drugs is often seen as the most pragmatic and direct response. Unfortunately not all drug donations are helpful and inappropriate drug donations can be dangerous or

useless, and a source of problems for the recipients”. The *Guidelines*, which are endorsed by the Australian Pharmaceutical Advisory Council, are intended to ensure that Australia is never guilty of sending inappropriate donations. The *Guidelines* are based on three core principles (see box).

Core principles for donations

- ◆ A donation is intended to assist the recipient. Donations should be based on an expressed need. Donor-initiated donations where the recipient's advice has not been sought are unhelpful.
- ◆ Donations must support essential drugs policies. Respect must be given for the authority of the recipient and the receiving country's administrative arrangements.
- ◆ There should be no double standards. If the quality of an item is not acceptable in Australia it is unacceptable as a donation. Therefore any collection and redistribution of patients' unused medicines is not permitted.

The Australian *Guidelines* emphasise that the most appropriate response to appeals for help or ongoing assistance to developing countries is a financial contribution. “It is usually cheaper for drugs to be purchased locally, or from specialist, non profit procuring agencies which are closer to the scene. Local procurement, which involves only a fraction of the transport costs encourages locally sustainable drug availability and support for local industry, is a more development oriented approach...In emergencies the most appropriate action may be the purchase of WHO Emergency Health Kits”.

On selection of drugs, these *Guidelines* supplement the interagency ones by stating that: “A written request should be obtained from a competent authority in the recipient country”, and that “The health facility receiving the drugs should be required to acknowledge receipt of the donated medicines”.

A special note has been included on vaccine donations, describing them as inappropriate because of the logistical problems associated with transport and storage. “Donations of money for purchasing vaccines are more helpful, so cold chain facilities can be put in place, and the right quantity and type of vaccine and associated supplies can be ordered at the right time”.

Quality and shelf-life

All donated drugs should comply with quality standards in both the donor and recipient country, and should all have a remaining shelf-life of at least one year after arrival in the recipient country.

Australia requests that product information and consumer product information (where available) be included for each of the drugs sent. “Many health facilities in developing countries do not have access to current, complete and accurate drug information. Where national treatment guidelines are not in use, it is important that prescribers and dispensers are provided with this information to ensure safe use”.

The *Australian Guidelines* conclude with detailed sections on export and transport of donations.

“All drug donations should be packed in strong outer cartons and be accompanied by a detailed packing list which should specify the contents of each carton by generic name, quantity and expiry date. Cartons should be numbered and the contents of each carton listed in detail in the accompanying documents. In addition, the contents of cartons should be marked on the outside of the cartons, preferably using a code system” (to discourage pilfering).

“Preparation for consignment of goods must be undertaken in close cooperation with the recipient, to determine



340 tons of drugs arrived during the civil war in Bosnia, most were unusable and had to be destroyed

the transport and clearance arrangements, documents needed by the recipient, and the costs that need to be met by the donor. The recipient will require advance details of the shipment's content and time of arrival. In most cases international transport, customs warehousing, clearance costs and internal transport will need to be paid by the donor. However, in some cases the recipient is able to cover clearance and internal transport costs. Agencies should make their own arrangements to comply with customs documentation requirements at all dispatch, transit and entry points.” □

Reference

1. Guidelines for drug donations. Geneva: World Health Organization, 1996. WHO/DAP/96.2.

SUPPLY

Time for evaluation

IN May 1996 the World Health Assembly requested WHO to evaluate experiences with the interagency *Guidelines for Drug Donations*, one year after their introduction. The *Guidelines* were finalised in April 1996, and widely disseminated in three languages: the English version in May, the French in August and the Spanish in September. The evaluation of experiences started in August 1997 and will be completed by June 1998. The most important component will be a carefully designed questionnaire. This will be pilot tested prior to distribution to all those who contributed to and commented on the first edition of the *Guidelines*, as well as to organizations and individuals who express interest in being included in the evaluation.

Specific emphasis will be put on the experiences of donation recipients. Apart from general and specific questions on practical experience with the *Guidelines*, four important aspects will be covered. Questions will be asked about national and local adaptations of the *Guidelines*. For example, national guidelines have already been published in Australia, Norway, Tanzania and Zimbabwe, and Ethiopia has adapted the *Guidelines* to be part of its National Drug Policy. The evaluation will also put emphasis on discovering: the practical benefits resulting from introduction of the *Guidelines*; the magnitude and beneficial effects of drug donations; and information on drug donations which have been hampered, delayed or cancelled.

Readers who wish to contribute to the evaluation should contact the Action Programme on Essential Drugs for a questionnaire. □

Vaccine donations: maximising the benefits

As more countries adapt the interagency *Guidelines on Drug Donations*¹ to meet their own requirements, the need for a similar policy on vaccines has been recognised. WHO's Global Programme for Vaccines and Immunization has issued a set of guidelines² which illustrate "Good Donation Practice" on the part of both donor and recipient. There are many reasons for sending vaccine donations, including emergencies, such as disease outbreaks and wars, or sudden shortages of stock during supplementary immunization activities, corporate donations, or bilateral aid. The benefits of donations, when they are properly managed, can be enormous, but donations can also leave a country vulnerable to problems (see box).

Although the scenarios in which they are given differ, WHO asserts that the same basic principles should be considered whenever a donation is to be made.

For the most part, the interagency *Guidelines for Drug Donations* are applicable for vaccines as well. The four core principles for drug donations (maximum benefit to the recipient; respect for the wishes and authority of the recipient; no double standards in quality; and effective communication between donor and recipient;) have been expanded into 12 guidelines that also apply to vaccines. In addition four minimum specifications for vaccine donations are recommended:



It is essential that donations of polio vaccine are protected from heat, especially in tropical conditions

The vaccine should:

- ◆ be consistent with the goals of the immunization programme;
- ◆ be subject to prescribed licensing and control procedures established by the recipient government;
- ◆ meet all specifications consistent with other vaccines in the programme, including potency, presentation, transport, shelf-life, number of doses per vial, thermostability and labelling;
- ◆ be shipped only on request of the responsible national officials.

National controls needed

Most recipient countries are dependent on UNICEF and other donors for their vaccine supply, yet many currently lack the infrastructure to handle donations adequately. This problem must be addressed if the new guidelines are to succeed. WHO recommends that all countries exercise at least two essential national control functions: they should issue a set of requirements for licensing; and undertake surveillance of vaccine field performance (including monitoring of adverse events following immunization).

A successful vaccine donations policy needs a focal point to check vaccines upon receipt, with the ability to refuse those not meeting national criteria. This means that criteria, such as licensing requirements, must be drawn up, published and applied. A system to detect and investigate complaints from the field must be put in place. Developing a vaccine donations policy reinforces the need for and functioning of a national vaccine control system.

WHO's role

WHO, through its headquarters, regional and country offices, can provide technical advice and advocacy for the adoption and implementation of a vaccine donations policy. It can do so particularly in the areas of information dissemination, policy adoption, advocacy with donors as to the suitability of donations, training and monitoring implementation. WHO can also provide a rapid response for investigating and resolving problems with donated vaccines.

Working in partnership with WHO, donors and recipient countries can ensure that the new guidelines achieve their aim to improve the management of donated vaccines. □

Copies of *GPV Policy Statement: Vaccine Donations* are available, free of charge, from: World Health Organization, Global Programme for Vaccines and Immunization, 1211 Geneva 27, Switzerland.

1. Guidelines for drug donations. Geneva: World Health Organization, 1996. WHO/DAP/96.2.
2. GPV policy statement: vaccine donations. Geneva: World Health Organization, 1997. WHO/VSQ/97.05.

Problem donations

- In one country counterfeit meningitis vaccine was donated by a neighboring country at the peak of a meningitis outbreak. The counterfeit vaccine was ineffective at best, and at worst caused harm to the recipient. In either case, public confidence in the immunization programme was threatened.
- Bacille Calmette-Guérin vaccine with no remaining shelf-life was donated to an African country by a nongovernmental organization. Vaccines donated which are at the end of their shelf-life generally cannot be used. If they are sent to immunization centres, staff will either have to ignore their training, which tells them to follow the expiration date, or not use the vaccine. The result either undermines training and good immunization practices or a large amount of vaccine must be destroyed.
- A large donation of oral poliovirus vaccine suffered a cold chain break in transport. In this case, the vaccine was donated, at WHO's request, by a manufacturer for a polio national immunization day. Normal precautions had not been taken to guard the potency of the vaccine throughout transport to the recipient country. The result was that the cold chain was broken, the vaccine could not be used, and the national immunization day had to be postponed.

Formal requirements for donations in Norway

IN Norway, the Board of Health has drawn up national guidelines which are very similar to the interagency guidelines on drug donations. However, two important additions have been made:

- donations should as far as possible be channelled through major organizations with experience and expertise in the field
- an export licence from the Board of Health is required for all exports of medicines from Norway, including donations. (This has been a requirement for some time, even before the interagency guidelines were issued). The Board will only consider issuing an export licence for a donation if, as a minimum, the following conditions are met:
 - the donor submits a written consent from the health authorities in the recipient country
 - the donation does not contain any

medicines returned by patients or given as free samples to health professionals

- the donated medicines have a remaining shelf-life of at least one year after arrival in the recipient country (this is the general rule, exceptions can be made)
- quantities are adapted to the need of the recipient, so that the donated medicines can be used in the ordinary supply system of the recipient)
- all medicines are labelled in a language understood by the recipient, and each container is labelled with the generic name/active ingredient, strength, dosage form, quantity, manufacturer, storage conditions and expiry date
- the donation is accompanied by a list, written in a language understood by the recipient, specifying each product by generic name/active ingredient, strength, dosage form, quantity, manufacturer, batch

number and expiry date. The products should be grouped by therapeutic category e.g. ATC classification system

- the medicines in the donation have been evaluated by a professionally qualified pharmacist, and packed in a professional and suitable manner; the recipient has agreed to the shipping

The Norwegian guidelines were finalised after a draft had been discussed at a meeting with the interested parties, including donor organizations, pharmaceutical and medical associations, the pharmaceutical industry association, importers, exporters, wholesalers and the Ministry of Foreign Affairs.

The guidelines came into force at the end of May 1997, when the Board of Health issued a circular about them to major donor organizations, pharmaceutical and medical associations, the pharmaceutical industry and wholesaler associations, and pharmacies. □

RATIONAL USE

International Conference on Improving Use of Medicines



THE first International Conference on Improving Use of Medicines (ICIUM) was held in Chiang Mai, Thailand, from 1–4 April 1997. The conference brought together a wide range of participants, and a wealth of interesting and important material and ideas about improving the use of medicines. This issue of the *Monitor* draws on the papers and discussions at ICIUM to give readers an overview of the main themes discussed there, the lessons drawn and the recommendations made about the future direction of work to improve the use of medicines.

ICIUM: STATE OF THE ART AND FUTURE DIRECTIONS

For more than 20 years WHO and other international organizations have advocated the essential drugs concept, and promoted and supported national essential drugs programmes. Initially much energy and resources went into improving systems for selection, procurement and distribution of safe and effective drugs. During this time relatively little thought was given to how the drugs were used. The Nairobi Conference of Experts in 1985 stressed the importance of the rational use of drugs, emphasising that essential drugs could also be poorly used. The Nairobi meeting brought drug use into the foreground. Since then much has been done to try to improve the way in which drugs are used.

The organizers of ICIUM felt that it was important to bring together and evaluate experience in this field, and to describe the "state of the art" in relation to improving the use of medicines. They felt that this would help to define promising future directions for those involved in research and policy. The organizers aimed:

- to synthesise the evidence for success of different strategies to improve use of medicines in developing countries;
- to develop policy guidelines for implementing proven strategies; and
- to identify important directions for future research.

This conference drew upon experience from different countries, disciplines and

sectors to develop an overview of work to improve drug use. It also provided an excellent opportunity for networking and the exchange of experiences. In addition it gave participants a chance to identify others with common interests, and to lay the foundations for future partnership and collaboration.

A SENSE OF URGENCY

The conference opened with several speakers emphasising that improving rational drug use was no academic exercise but a matter of life and death. Professor Pakdee Pothisiri, Secretary General of the Thai Food and Drug Administration, stressed in his welcoming speech that rational drug use is an immediate need, and Dr Jonathan Quick, Director of the Action Programme on Essential Drugs, emphasised that people are dying because they are misdiagnosed, underdosed or overdosed. He stated that problems need to be addressed urgently, and with the collaboration of all parties. He also stressed that diversity, creativity and an evidence-based approach are essential in the search for strategies and solutions.

Dr Dennis Ross-Degnan, who coordinated the scientific programme of ICIUM, briefly explained how the idea of this conference was born. Rational drug use topics had only been part of larger conferences on pharmacology and clinical pharmacology. However, immediately after the Sydney International Conference on National Medicinal Drug Policies in 1995, the International Network on the Rational

Use of Drugs (INRUD) and the Action Programme on Essential Drugs decided to organize a first global conference focusing solely on rational drug use in developing countries (see box 1).

UNDERSTANDING DRUG USE: LEARNING FROM DIFFERENT PARADIGMS

Early efforts to improve drug use tended to assume that irrational use was largely due to lack of knowledge, and that the simple provision of information would be a remedy. But it soon became clear that the reasons for irrational drug use were complex and multi-factorial, and included a mass of social and cultural factors, perverse economic incentives and promotional practices. Professor Chitr Sithi-Amorn, who chaired the local Conference Coordinating Committee, described the barriers to appropriate drug use and emphasised that there had been important changes in the context in which health systems operated. Governments had become less important as providers and more important as regulators and organizers of the pharmaceutical environment. These changes added to the complexity of the problems facing those who try to understand and influence drug use. Complex problems demand complex strategies, and different disciplines can contribute to an understanding of patterns of drug use and misuse.

A multi-disciplinary approach was therefore at the heart of the conference agenda, and paradigm papers were presented early on in the conference to underpin this approach. Behaviour can be interpreted according to different models, for example, the biomedical model, and while each of these models, or paradigms, can be enlightening each also has its weaknesses and limitations. Those who operate within a particular paradigm often do not realise the extent to which it shapes their views and determines their strategies. Opportunities to step outside the limits of any particular model can provide us with added knowledge and understanding of what shapes medicine use and how to influence it. Conference participants were not asked to "judge" the paradigms but to learn from each of them, and to use the different models to build a multi-disciplinary framework within which to improve drug use. Some of the central ideas from the five paradigm papers are summarised below.

Biomedical

"I mistrust what I cannot test, discount the subjective as soft and am constantly seeking hard evidence, clearer definitions."

The biomedical model has strongly influenced much research into drug use. Within this model things either exist, or do not exist or are not relevant. Hypotheses can be proven or discounted and if something cannot be measured or tested then it

is to be mistrusted. Problems can be solved using a deductive not inductive approach. If we want to understand or influence a phenomenon the limits we experience are the limits of our knowledge of why things happen and our ability to measure them.

The biomedical paradigm offers certainty and reason and brings with it important tools. Perhaps the most important of these tools is the double blind randomised controlled trial, which is seen as the ultimate "gold standard" for evidence, because it eliminates chance.

Drug use often appears irrational and those working within a biomedical paradigm will see irrational behaviour as a disfunction which can be diagnosed and treated. The biomedical perspective seeks to correct the behaviour of those who use drugs irrationally, whether they are doctors who do not prescribe rationally or patients who do not do as advised.

The biomedical paradigm is convincing and attractive but it has its shortcomings. These include an assumption that science and scientists are neutral. An assumption which is not born out by history or by the way in which scientists sometimes cling to outdated and highly irrational ideas. Another shortcoming is that it can encourage a narrowness of vision and an unreasonable certainty. Within this paradigm a doctor who can find no evidence for a patient's symptoms is inclined to conclude that the problem does not exist. A biomedical approach has also encouraged the practice of medicine which treats the part not the person, which treats a tumour but may not see the cancer patient.

The biomedical paradigm is immensely powerful but needs to be tempered by other models if we are actually to work with real people in real settings, and aim to improve health through the use of medicines rather than just improving medicine use.

Community action

"Patients have a right to know what drugs are used on them, what they do to them, and what are the possible benefits and harm that can accrue from the use of drugs."

This model stresses empowerment and participation as key concepts. Those working within this paradigm work from the assumption that the answers to most health problems lie not in technical or scientific breakthroughs but in reaching people and increasing their control over their lives. Within this paradigm drugs are seen as an important part of the therapeutic process. However, it is argued that the power of the medical profession has led to a mystification of medical processes and encouraged the development of a "pill for every ill" mentality. Technological advances have meant that increasingly complex drugs can be designed but a system of production has developed in which the process has been alienated from the people. Production of new drugs means ever increasing research and development costs, together with a

Box 1

About the Conference

ICIUM was attended by 272 researchers, policy makers and health managers from 46 countries, representing a range of interests including universities, ministries of health, nongovernmental agencies, consumer organizations, donors and the pharmaceutical industry. Participants attended five plenary sessions, chose between 25 workshops and could view 148 abstracts and posters which had been prepared for the conference.

International co-sponsors included WHO's Action Programme on Essential Drugs and the International Network for Rational Use of Drugs (INRUD), which together planned the scientific programme, the United States Pharmacopeial Convention (USP), and the Applied Research on Child Health Project (ARCH). ICIUM was organized locally by a consortium that included the Thai Food and Drug Administration, the Thai Network for Rational Use of Drugs, Chulalongkorn University College of Public Health and Chiang Mai University.



vicious cycle of heavy marketing and rising prices. The role of physicians has been fundamentally altered by their dependence on a powerful health care industry. Community action aimed at improving the use of medicines should start by demystifying drug issues and should end the dominance of medical practitioners, professional and commercial interests. How best to organize community action will vary greatly in different social and cultural settings. Those who operate within the paradigm of community action see science as a tool for social revolution, if it can be brought to people in their communities.

Socio-cultural

"To say that the potential for collaboration exists is one thing, but getting at the politics of the possible is another."

This model stresses the cultural and organizational environment in which medicines are used and produced. Social trends, such as the medicalisation of social problems and the tendency to see health as a commodity, are seen as important influences on behaviour. Local health cultures and beliefs are also important in determining how people see and use drugs.

The way in which drugs are used is complex and cannot be viewed in isolation. People consume medicines for a variety of purposes and practitioners have a number of reasons for prescribing them. The way in which people use medicines is not determined by knowledge alone. Medicines, like other commodities, take on values in relation to status and identity, promises, social and cultural meanings as well as their economic cost.

Changing the way in which medicines are used requires understanding a range of social and cultural factors including:

- ◆ expectations of medicines and the factors which foster such expectations;
- ◆ cultural interpretations of how medicines work and when they should and should not be taken;
- ◆ interpretations of the attributes of medicines (such as colour and taste) and the way in which they influence their use;
- ◆ self-medication practices;
- ◆ differences between practice in the private and public sector;
- ◆ the way in which new products are developed in response to changing health concerns and the way in which these concerns change;
- ◆ marketing strategies within the health care system.

If we understand these and other social and cultural factors it will help us to analyse the complexities which underlie patterns of drug use. Only then can we tackle some of the problems related to drug use. We need to find strategies to address these problems which cannot be ignored and require immediate action.

Economic

"While a clinical perspective focuses on the individual patient who requires treatment, economics is concerned with the most appropriate use of resources to achieve the greatest benefit for society as a whole."

The economic paradigm's starting point is the recognition of the scarcity of resources. The focus of economics is choice. Economics is not concerned with cost containment but rather with efficiency and the allocation of resources to achieve the greatest benefit for society as a whole.

Economic evaluation provides a framework for explicitly considering the

economic implications of different options. At present many decisions about the use of scarce resources are implicit and the evaluation of costs and benefits is not transparent.

Economic evaluation seeks to overcome this. However, economic evaluation is not intended as a decision making machine but as a way to provide information to help decision makers. There will often be other considerations (arising from paradigms other than the economic one), which have to be taken into account and which may override economic priorities.

The key economic objectives of health care are efficiency and equity, so the economic model views the broad problems with medicine use in terms of inefficiency and inequity. Resources are used inefficiently if they are not allocated to achieve the maximum health care benefits. Resources are also used inefficiently if a given outcome could have been reached at lower cost. From the perspective of medicine use an essential drugs list is a useful and efficient strategy because it gives priority to cost-effective medicines necessary for treating the major health problems within a country.

Technical efficiency can be promoted by improving logistics, prescribing guidelines, treatment protocols and by eliminating perverse incentives. Cost sharing incentives to consumers have some effect in reducing demand but incentives to providers are much more powerful tools.

Equity can be defined in different ways. A system can be considered equitable if those with equal need receive equal treatment, but also if resources are targeted at those in greatest need. The effect of user fees on equity is of particular concern in the use of medicines.

Economic evaluation is a young and rapidly developing science and there are shortcomings in the economic paradigm. Economic evaluation requires substantial data collection and depends on being able to measure health benefits in a way which people can agree with. The results of economic evaluations need to be regularly updated and the evaluations themselves are open to manipulation and to different interpretations. Improved awareness of economic concepts among clinicians is important, as pharmaceutical companies increasingly include economic data in marketing material.

Political

"Through open, honest, thoughtful and productive development dialogue, we must direct our efforts at reconciling private gain with public good, professional pride with patient welfare, science with value."

Politics is the process through which individuals or groups clarify and articulate their priorities and how they organize and mobilise to achieve these. Typically a political problem is one that involves numerous stakeholders with multiple, usually conflicting interests that demand ordering and balancing. The political paradigm is therefore an integrating concept which can bring different dimensions together.

Drugs represent more than chemicals or biological substances with therapeutic capacities. They are also objects of study and discovery, symbols of professional power, marketable products with intrinsic commercial value and instruments of national policy. The roots of irrational drug use are



An appreciative audience at ICIUM – the conference brought together researchers, policy makers and health managers from all over the world

Photo: College of Public Health, Chulalongkorn University

embedded in the complex interrelationships that exist between patient, physician, drug manufacturer and government. Drug policy and issues related to the way in which drugs are used are highly political areas.

From a political perspective the problems associated with drugs' consumption and production can be reduced to tensions arising from conflicting interests where, for the most part, the more powerful stakeholders win out.

It seems inevitable that there will be winners and losers, but this should be avoided wherever possible because political systems are highly complex and interrelated. The interests of different stakeholders are deeply connected and interdependent even when they may appear to conflict. It is important to look for strategies through which everybody can gain even if they do not gain equally. In general we should always try to choose the strategies in which the weakest stand to gain the most.

Changing attitudes and policies in the health area is a challenge and the heart of the challenge is about talent scouting, recruiting, nurturing and supporting leaders in this field. It is necessary to develop a new way of thinking and acting, to redefine the health sector's priorities, and to mobilise the sector's resources to achieve these priorities.

The other paradigms describe the state of the art. The political paradigm enables us to integrate the rich variety of the perspectives and their interactions, and helps us to prioritise them so that we can make choices about our future directions – in essence this is the political paradigm at work. Politics, because it is ultimately about people and relationships is a force that can be as integrative and unifying as it can be divisive and disruptive.

COMPLEMENTARY AND CONFLICTING MODELS

Reacting to the paradigm papers an expert panel stressed the importance of integrating and reconciling different perspectives. The paradigms described are sometimes complementary, but at other times seem to directly conflict with each other. Someone who works within the biomedical model may find it difficult to accept the approach of the economist, who looks at health outcomes for populations rather than patients. Equally, someone working within a more social cultural framework may find the biomedical model inflexible and inapplicable to real people in real situations. There are many problems and causes of inappropriate medicine use that any individual paradigm is unable to address. But a greater recognition of the contributions of the range of paradigms and their input into decision making processes will promote an improved use of medicines.

Anyone who wishes to work to improve rational drug use would be well advised to learn from different paradigms. It may then become easier to understand better why doctors continue to adhere to non scientific practices, and why for some consumers it may seem a very rational choice to buy single tablets from a street seller. Those who adhere too rigidly to any model are likely to be disappointed, those who try to learn from several will be better able to anticipate constraints, understand other perspectives, collaborate, and develop creative solutions and strategies. The panel reacting to the paradigm papers also stressed that rational use of drugs is not an end in itself. The important goals to be pursued are health and equity. Rational drug use, efficiency, cost-effectiveness, evidence-based medicine and community participation can all help in achieving these goals.

The following paradigm papers were presented at the conference:

- Biomedical: Dr A. Mant, School of Community Medicine, University of New South Wales, Australia.
- Community action: Professor B. Ekbal, Department of Neurosurgery, Medical College Hospital, Kottayam, India.
- Socio-cultural: Dr M. Nichter, Department of Anthropology, University of Arizona, USA.
- Economic: Dr D. McIntyre, Health Economics Unit, University of Cape Town, South Africa.
- Political: Dr A. Bengzon, The Medical City, Manila, Philippines.

Box 2

Some paradigm and review papers presented at ICIUM will be published in a special supplement of an international journal. More information will be provided in the next issue of the *Monitor*. Abstracts and authors' addresses are available at the ICIUM web site (see end of article). A printed list is also available from the Action Programme on Essential Drugs.

EXPERIENCE FROM THE PAST – LESSONS FOR THE FUTURE

One of the conference objectives was to describe, evaluate and synthesise experiences in improving the use of medicines. In the run-up to the conference reviews were carried out to summarise the findings from published and unpublished studies in six important areas:

- Impact of pharmaceutical policies and regulations on use of medicines;
- Impact of economic policies and incentives on use of medicines;
- Improving use of medicines in hospitals;
- Improving use of medicines by primary care providers;
- Improving patients' use of medicines;
- Improving consumers' use of medicines.

Interventions to improve drug use in each of these areas were identified. The interventions selected for review were ones which focused on the use of medicines, which included a policy or programme intervention, which included an assessment of impact and which were based on developing country data. The methodologies of the studies were assessed and experiences from the studies compared. Where possible, conclusions were drawn about which strategies worked and which did not.

cont'd on pg. 8

Finally, important gaps, both in the knowledge from studies and in appropriate methodologies, were identified.

The reviews themselves varied in their scope and findings. In some areas it was possible to identify a relative wealth of studies. In other areas there were very few studies and even fewer which met the minimum methodological criteria defined for the review, (see box below). None the less, each of the reviews was able to draw some conclusions about what was known, what was not known and what lessons could be drawn for the future. Taken together the reviews give a comprehensive overview of research carried out in developing countries, about improving drug use. Some of the main findings of the review papers are summarised below, together with points which arose in the discussions at the conference.

Box 3

The authors of each review agreed on criteria by which to assess the methodological adequacy of the studies. For example, the authors of the review of interventions to improve the use of medicines by primary care providers used the following criteria. Studies which met the definition for methodological adequacy included: randomised controlled trials, pre-post studies with a non-randomised comparison group, time series (with or without a comparison group) which used at least four measuring points. Studies which were considered methodologically inadequate included pre-post studies without a comparison group and post-only studies with or without a comparison group.

1) Impact of Pharmaceutical Policies and Regulations on Use of Medicine

A variety of policy instruments have been developed in attempts to improve the availability, affordability, quality and the rational use of medicines. The literature in this area was reviewed in order to synthesise experiences and examine the evidence for the success of various measures, so that lessons could be drawn for the future.

The articles and reports which were analysed fell into three broad categories:

- ◆ multi-component national drug policies;
- ◆ drug supply and cost sharing programmes;
- ◆ regulatory measures.

The majority of the studies were evaluations of programmes and were carried out solely on the basis of post-intervention measures. This means that no hard conclusions could be drawn about the impact of the policy measures.

A review of supply and cost sharing programmes illustrated that very different results can be produced. The review authors suggested that the differences could be explained partly by the inclusion, or non inclusion, of a training element. In other words if there is no prescriber education, simply supplying drugs to health facilities may not lead to improved drug use.

A review of the studies on legal measures also produced mixed results. Deregistration can be effective in reducing the use of a drug but may produce unfavourable secondary effects. In Pakistan it has been suggested that the banning of antimotility drugs led to an increase in the inappropriate use of antibiotics in diarrhoea, but the available studies do not provide evidence to test this hypothesis. Conversely

switching a drug from prescription only status to over-the-counter (OTC) may give greater access to the drugs but this does not necessarily lead to more appropriate use.

Results from evaluations of the various national drug policies are mixed. WHO, the Karolinska Institutet and Harvard School of Public Health coordinated a 12-country comparative analysis. The study¹ gives a cross sectional assessment of drug systems in each country, using indicators derived from the WHO manual, *Indicators for Monitoring National Drug Policies*² and also using the technique of "political mapping" to analyse the policy making processes. Some programmes were judged to be working well while others were not (see box). Policies which seemed similar produced very varying results, but the study designs and available data were insufficient to explain the variations.

Box 4

Comparative analysis of national drug policies: examples of data from the 12-country study.

A selection of indicators were used to assess availability, affordability, quality and rational use of drugs. Wide variations were found, including:

Availability. The percentage of certain essential drugs available in a sample of remote health facilities ranged from a low of 54% in the Philippines and 54.8% in Zambia to 100% in Sri Lanka.

Quality. The percentage of drugs that failed quality control testing was found to be 13% in Sri Lanka, 25% in Viet Nam but 65% in the private sector in Chad.

Drug use. The average number of drugs per prescription was 1.95 in Bulgaria and 2.39 in Colombia. In public facilities in Zimbabwe 13% of prescriptions contained at least one injection, in Viet Nam it was 31.9%.

A complex area for researchers

The review identified only a few studies in the area of drug policy which were judged methodologically adequate. It was suggested that this was partly due to the complexities of the policies themselves. Four major difficulties were identified, which have to be overcome in studying the impact of national drug policies:

- Most national policies addressing problems of drug use have an indirect multi-step causal relationship with the ultimate goal of rational drug use. For the policies to be effective each of the causal links must be valid. Evaluation of the policies often looks at the intermediate steps rather than the changes in drug use.
- Most national drug policies consist of several measures aimed at addressing various related problems. It is difficult to separate these measures and their impacts. Indeed the impact of an integrated policy may be more than the sum of the impact of individual measures.
- If a policy intervention fails it can be difficult to determine whether the policy was ill conceived or poorly implemented.
- National policies are large social experiments which affect whole populations. There is usually no reliable control group to enable comparisons. A rigorous design would need to examine trends at national level prior to the

introduction of the policy and determine whether there was a change in trends during and after implementation. The best example to date is the 10-year series of biennial national surveys from Zimbabwe.

These are major constraints inherent in the evaluation of national policies. In the absence of studies which overcome these constraints it is not possible to provide hard evidence that national drug policies improve drug use. The authors of the review argue that in spite of the difficulties inherent in evaluation of national policies, stronger research designs could and should be used. National policy interventions should not be carried out only on the basis of logic and theory but should be tried and tested. Discussions at the conference emphasised the need to develop multi-method evaluations which incorporate qualitative methods, and stressed the need to improve data collection on the policy environment and the political context of regulatory change. The point was also made that even if evidence of the impact of national drug policy is lacking this does not mean that national drug policy is not important. There are indeed strong arguments to support the common sense view that a coherent policy framework and well functioning regulatory systems matter a great deal, and facilitate the success of interventions to improve drug use. Better monitoring of the impact of policies, using the standard indicators which have been developed and tested, will provide valuable information for those involved in policy implementation.

Box 5

Monitoring the impact of essential drugs programmes

In 1988, after a base line survey, the Zimbabwe Essential Drugs Action Programme set up a sentinel system to provide feedback on drug availability. This was expanded in 1989 to measure the impact of training programmes as well as rationalisation in the supply system. Staff at central and provincial levels participated in the development of a survey methodology and its implementation. A stratified random sample of primary health care facilities and district hospitals is regularly surveyed. Key indicators include:

- availability of essential drugs;
- application of the national stock control system;
- lead times and delays within the drug distribution system;
- drug prescription and use.

These surveys, which provide a wealth of information about the status, strengths and weaknesses of the national programme over time are a model of how essential drugs programmes can effectively monitor and evaluate impact.

Policies and regulations for improved drug use – lessons learnt

In spite of the limited evidence available some conclusions and lessons emerged from the review, and from discussions and presentations at the conference. It was agreed that it is possible to improve the use of medicines through targeted regulatory interventions, but enforcement of existing regulations is generally weak, and the impact of regulations on drug use is rarely evaluated. A generics policy is necessary, possible to implement and can influence

both public and private sector practice, but it should be implemented stepwise with intensive interaction with stakeholders. Political will, stability, the involvement of stakeholders and appropriate timing are important for the success of national drug policies. A strong consumer movement and supportive media are important factors in implementation, and in the eventual success of drug policies.

It was stressed that it is necessary to develop methodologies to help understand the processes and impact of policy, and to aid evaluation and monitoring. The use of agreed indicators can help in monitoring the implementation and impact of national drug policy. It is essential to understand the political processes at work and to develop strategies to mobilise support for implementation. There should be better collaboration between policy makers, researchers and stakeholders to strengthen the link between theory and practice, between science and political reality.

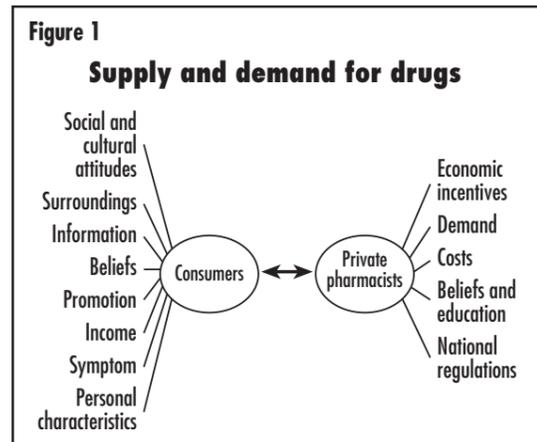
2) Impact of Economic Policies and Incentives on Use of Medicines

Drugs and money are inextricably entwined. Everyone who uses, prescribes or dispenses drugs is influenced by economic factors, and these affect the way in which medicines are used. Consumers' decisions are influenced by their income, by their perceptions of a drug's value and by other factors. Pharmacists and private drug sellers are influenced by profit margins, by promotional activities, incentives and basic business economics. Prescribers equally are influenced by what they know about drug prices, by promotional activities and incentives. User fees and other forms of financing and insurance mechanisms affect drug usage. Pharmaceutical manufacturers are influenced by the economics of drug development, marketing and registration.

Figure 1 (see page 9) illustrates examples of the complex factors influencing supply and demand for drugs.

All of these factors are important in determining drug usage, but few of them have been the subject of systematic research. For this reason the ICIUM review focused particularly on one area: the impact of user fees. This is an area which has been the subject of considerable research, and studies are available which are in keeping with the criteria defined for the review. Thirty-two reports were found which dealt with fees for drugs, but few reports assess the impact of user fees on drug use, and the studies are generally based on limited data. The review analysed the findings of six user fee programmes which did present quantitative data on drug utilisation, drugs per patient and other drug use measures.

These studies on user fees and their impact on drug use show that the number of items prescribed for each consultation varies with the fee type, fee level and the payment status. When looking at the number of drugs prescribed, the total was lower in schemes which charged a fee per item than in control groups or in groups which were charged a flat fee per case. A study from Kenya showed that the introduction of a fee per item led to a reduction in the number of items dispensed per encounter, but this did not result in the reduction of the number of encounters with an injection. In Zimbabwe, the number of drugs per encounter was directly related to payment status, with exempt patients receiving the most drugs and full-pay patients receiving the fewest drugs.



Source: Cederlof C, Tomson G. Private pharmacies and the health sector reform in developing countries. *J Soc & Admin Pharmacy* 1995; 12: 101-11.

An alternative to user fees is health insurance but, in developing countries, the use of insurance varies greatly by region and country. In Sub-Saharan Africa, for example, only 8% of the population in countries with health insurance is insured, while in Latin America over one-third of the population is covered. Insurance schemes can encourage over prescription and over use of drugs, so it is important that ways are found to encourage rational use and keep costs down (see Table 1).

Promoting generic drug use is one important way of keeping costs down. Experience suggests

that, despite much effort to promote generic drug use, the acceptance of generic prescribing and dispensing has been slow in most countries. Building a large generic market takes time, even in industrialised countries. Doubts about drug quality assurance can undermine policies to promote generic use.

Table 2

Mechanisms for promoting generic drug use

Area of intervention	Activities
Supportive legislation and regulation	<ul style="list-style-type: none"> • abbreviated registration procedures • product development while patented • generic labelling • generic substitution
Reliable quality assurance capacity	<ul style="list-style-type: none"> • equivalence lists • national quality assurance capacity • GMP enforcement
Professional and public acceptance	<ul style="list-style-type: none"> • involvement of professional groups • phased implementation • all training by generic name • public promotional information
Economic incentives	<ul style="list-style-type: none"> • price information • higher generic retail margins • use of generics by insurers • development of generic industry

Source: Review paper 6 (see page 11)

Price controls also have a role to play, and are common in both developed and developing countries, although various secondary effects can result. The impact of price controls on total expenditure and on drug use is uncertain.

Registration fees have been introduced in some countries in an effort to rationalise the drugs marketed. There are major differences in the level and structure of registration fees. In Latin America fees vary from nothing to US\$ 4,000. Very little is known about how differences in fees and fee structures affect the range of drugs on the market and, thereby, drug use.

There is a great deal of descriptive literature and popular opinion describing the relationship between economic factors and drug use, but there are very few studies which systematically link economic interventions to changes in drug use. In general there is still much to learn about economic approaches to improve the use of medicines through consumer decisions, dispensing practices, prescribing practices, drug financing systems and industry decisions.

A number of important issues did not fall within the scope of the review but were identified by the authors and conference participants. These included the economic consequences of irrational drug use; the economic benefits of rational drug use; and

economic aspects of supply and production. The economic consequences of macro policies, such as GATT/WTO, and the impact of global trends, such as liberalisation and privatisation, are major areas which are little studied and not well understood.

Lessons learnt

A number of lessons were drawn from the review and the discussions which followed. The impacts of user fees and cost sharing mechanisms on the use of medicines are complex. Some studies have shown that fees can lead to adverse impacts such as reduced access and inappropriate overuse, but if cost sharing is structured appropriately these can be avoided. A fee per visit tends to encourage overuse of drugs. High fees tend to be inequitable and affect the poor and children most. Levels of patient attendance depend on the level and type of fee and the perceived quality of care. It is important to define the objectives of user fee or cost sharing programmes when they are introduced and it is important to collect good baseline data before introducing fees

or other financing mechanisms so that the impact can be measured and understood. In general costs should be rationalised, and efficiency and quality of care should be improved before cost sharing can start.

It was also stressed that more attention should be paid to economic consequences when planning and developing drug policy. Increased use of cost-effectiveness analysis and pharmacoeconomics may help in priority setting. It is necessary to structure incentives thoughtfully and creatively in order to encourage rational drug use, rather than rewarding poor prescribing and dispensing.

3) Improving Drug Use in Hospitals

In developing countries there has been relatively little research on how best to improve drug use in hospitals. Much of the published research has focused on clinical research rather than quality improvement. The studies which have been carried out have often been based on weak study designs, which makes it difficult to draw hard conclusions or compare interventions. In other areas which were reviewed it was clear that research designs had improved during recent years. This was true of interventions studied at primary level but no similar improvement was found in studies which focused on hospitals.

About half of the interventions identified for this review were designed to address specific health problems such as: acute respiratory infections (ARI), diarrhoea, infections, or malaria. The other half focused, not on a health problem, but rather on an aspect of prescribing behaviour, such as the prescribing of generic drugs, antibiotic use, cost, polypharmacy and injection use. Various outcome measures were used including: cost, prescribing indicators, severity of illness and mortality. But none of the studies included in the review measured changes in knowledge, diagnosis or dispensing performance.

There were few studies at hospital level compared with the number of studies at primary care level. Given that hospitals are relatively easy sites to undertake research in, and that data collection is simpler compared to the primary health care level, this seems surprising. The authors of the review suggest that this finding is probably a

reflection of the fact that donors have tended to prioritise funding for research at primary level.

In fact there is a strong case for focusing attention on drug use in hospitals. Hospital pharmaceutical use is a major component of public drug expenditure. Primary health care services tend to be relatively under-funded and hospitals often account for 60-80% of public spending on drugs. Hospital specialists may not be primarily concerned with interventions aimed at reducing expenditure, but are more likely to be interested in interventions which aim to improve the quality of care offered through improved drug use.

Gaps in our knowledge

Both the review and participants at the conference identified areas where work is needed. In general there are relatively few studies concerned with improving drug use at hospital level. Little is known about which measures are effective in improving quality of care, rational use, cost-effectiveness or dispensing practices. As highlighted in the review there has been little work done to improve case management of chronic diseases.

Lessons learnt

Hospital data are accessible but not generally used; these data are an important source of information to measure the quality of drug use. From studies in developed countries it is clear that strategies such as hospital formularies, drug utilisation review, or clinical guidelines can be effective tools for improving drug use. Hospital Drugs and Therapeutics Committees have also been highly effective in developed countries, but there is little experience of working with them in developing countries. Training and technical assistance are needed to help develop this area of work. Multifaceted interventions targeting specific problem practices with simple behavioural messages seem the most successful in hospital settings. There is a need to develop practical methodologies which would encourage hospital-based studies. The development of separate indicators for rational drug use in hospitals and participatory training manuals for the development of hospital treatment guidelines would be useful. The principle of evidence-based medicine is becoming well established in medical schools and teaching hospitals, but it needs wider implementation in non academic hospitals and other levels of care.

Box 6

Different types and levels of user fees influence demand in different ways³

In Kenya demand dropped by 27% when a registration fee was introduced. When the registration fee was suspended, demand increased again, but never reached the pre-fee levels. When an item fee was introduced one and a half years later, demand was only slightly reduced, by 6%.

The studies give information about numbers of drugs and the impact of fees on patient behaviour, but they do not give information about the quality of prescribing, dispensing or patient use. In other words if, after the introduction of fees, drug use goes down we do not know whether unnecessary consumption has been reduced or whether people who need drugs are not getting them. Policies defining who should be exempt from payment of fees are often unclear and unsatisfactory.

One argument often used for cost recovery programmes is that drug availability will be increased but, in the studies reviewed, few programmes managed to recover the full non-salary recurrent costs. Fees often increase at a rate below inflation, and this means that over time less and less funds are available to replenish supplies.

Other important gaps in understanding

In addition to reviewing the literature on user fees the review and discussions at the conference identified other areas in which work is needed to examine the ways economic factors affect the use of medicines.

Table 1

Examples of interventions to encourage rational use of drugs in insurance schemes

Intervention area	Type of intervention
Prescribing practices	<ul style="list-style-type: none"> • essential drugs lists • non-reimbursable lists • generic prescribing • clinical guidelines
Dispensing practices	<ul style="list-style-type: none"> • generic substitution • dispensing limits • prior authorisation
Patient cost sharing	<ul style="list-style-type: none"> • co-payment (e.g. \$1 per generic drug, \$2 per brand drug) • co-insurance (e.g. 25% for life saving drugs, 50-75% other drugs) • deductible
Reimbursement controls	<ul style="list-style-type: none"> • maximum allowable cost • reference pricing • pharmacoeconomic analysis • provider budgets

Source: Review paper 6 (see page 11)

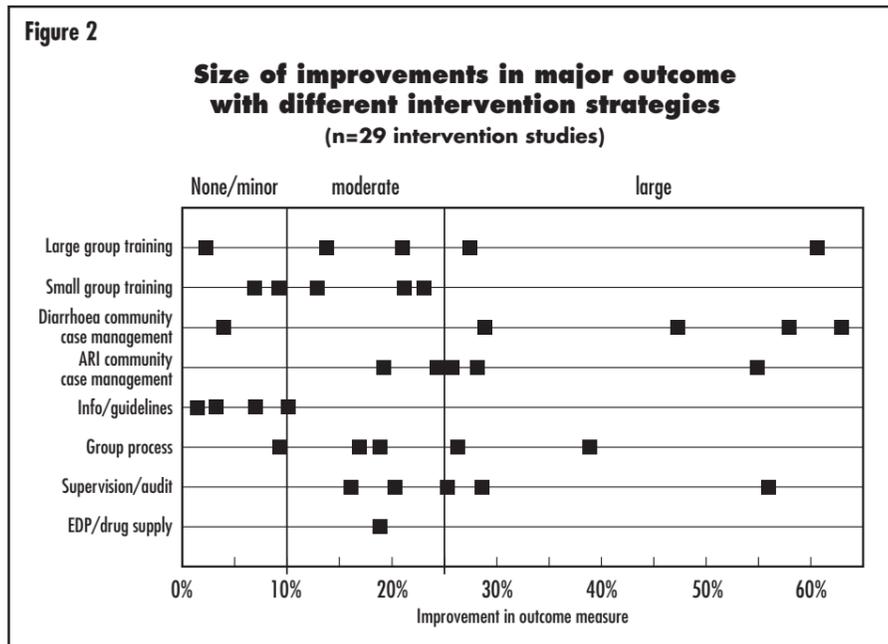
Box 7

Hospitals should become an important focus for strategies to improve drug use by:

- ◆ Promoting collaboration and information exchange between team members in hospitals;
- ◆ Facilitating the development of hospital Drugs and Therapeutics Committees, and evaluating their impact;
- ◆ Investigating the impact on drug use of hospital managerial interventions, such as drug management training, drug selection and supply systems and drug availability;
- ◆ Testing strategies for the effective implementation of standard treatment guidelines;
- ◆ Studying drug consumption and total treatment cost at hospital level.

cont'd on pg. 10





Source: Review paper 1 (see page 11)

4) Improving Use of Medicines by Primary Care Providers

At the primary care level, a relative wealth of intervention studies were identified and reviewed. Fifty-nine studies were identified of which 36 met the methodological criteria for inclusion in the review. The most frequent interventions were workshops or training courses, and interventions which were designed to improve community health workers' case management. Other interventions tested administrative or managerial strategies for improving drug use, such as supervision or audit and feedback.

In spite of the substantial number of interventions to improve drug use in primary care the breadth of experience is still limited. This is because most of the interventions targeted prescribing for a limited range of conditions, in particular: ARI, diarrhoea or, less frequently, malaria. Inappropriate antibiotic use was by far the most dominant prescribing issue addressed, followed by polypharmacy and injection use. Treatment of other health problems, chronic diseases, adult care and private sector practices were infrequently studied.

Large or moderate impact was measured in more than 75% of the studies with adequate designs. Only 21.4% of interventions had very low or no impact.

Box 9

Self-monitoring can be highly effective: an example from Indonesia⁵.

District staff trained and motivated health workers at rural clinics to collect and analyse their own prescription records. This was done on a monthly basis using three simple drug use indicators.

Over an 18-month period:

- ◆ Injection use declined by 56%
- ◆ Antibiotic use declined by 32%
- ◆ Number of drugs per prescription declined by 26%

Gaps identified

High quality studies of interventions to improve primary care drug use are increasing in frequency and there is consistent evidence for the effectiveness of various strategies. Much of the experience in this area has come from Asia and very little from Latin America. However, there are many crucial areas in which experience is limited and evidence lacking.

There should be greater attention to improving the use of medicine in adult populations. The focus should be broadened to include important chronic illnesses such as tuberculosis, sexually transmitted diseases, diabetes and hypertension.

Improving drug use in the treatment of malaria is an area which deserves more attention.

Most studies have been conducted in the public sector, and there is a lack of experience in trying to improve drug use amongst private practitioners. It is important to identify strategies which will work to improve drug use in the private sector. Methodologies and measurement approaches which may work well in the public sector may fail in the private sector where clinical records rarely exist.

More information is needed on the impact of national drug programmes and the implementation of national drug policies.

Box 8

A successful educational intervention in Mexico⁴

Errors in treating common diseases occur very frequently in primary health care practices, and can often result in increased prescribing costs. An educational strategy aimed to improve physicians' prescribing practices for acute diarrhoea (AD) and acute respiratory infection (ARI) was developed as a research study in Mexico, involving three medical care units. The strategy was largely based on promoting active participation of trainees in the whole process, including: group participation in a literature review of updated articles related to management of AD and ARI, and in the development of a clinical algorithm for the therapeutic management of these illnesses. Successful results as judged by the improvement of treatment practices and the maintenance of changes for up to two years after the intervention (as well as its ease of application and low costs) prompted extension to a health district and a State. Extension of the educational strategy was accompanied by a relative reduction in AD from 46.7% to 6.5% and ARI from 32.6% to 8.5%. The benefit-cost ratio showed a dramatic increase when comparing results from the research study and from the State intervention, for both AD (3.3% to 4.4%) and ARI (from 16.2% to 21.6%).

Zimbabwe has adopted a strategy which involves regular surveys to monitor programme impacts, and this could serve as a useful model for other countries. (See box 5)

More needs to be known about whether, and under what circumstances, interventions directed at prescribers result in better patient outcomes. Studies tend to concentrate on whether the prescribing and dispensing are appropriate, but little is known about whether patients do better when prescribing becomes more effective.

Not much is known about the cost-effectiveness of interventions. Simple standardised approaches need to be developed for collecting costing data, and for selecting the most feasible and relevant effectiveness measures.

During discussions it was stressed that little is known about the influence of commercial pressure and industry-sponsored conferences in shaping drug use. This was an important lack since research pointed to significant problems with unethical drug promotion, particularly in developing countries. And it appeared reasonable to assume, in view of the substantial sums expended by the pharmaceutical industry on drug promotion, particularly on industry-sponsored conferences and face-to-face sales promotion, that these were effective promotional techniques. It was also suggested that there was a need to involve medical associations, pharmacists' associations and retailer organizations in interventions.

Lessons learnt

A number of lessons were drawn from the review and from discussions at the conference.

Well designed training interventions, whether conducted in small or large groups, can successfully improve targeted prescribing outcomes by an average of 15% or more. The impact of training seems to be increased in interventions which used a mixture of training methods, (e.g. lectures, role play, problem solving), which focused on one specific problem at a time, which involved training at the place of work, and which used opinion leaders or district level staff as trainers. Community case management interventions for ARI and diarrhoea can help in reducing child mortality but their overall effects on appropriate drug use have not been well studied.

Managerial interventions based on group process, effective supervision or monitoring, and regular audit and feedback achieved consistently moderate to large impact on target practices. However, little is known about the broader effects of the interventions or sustainability of the improvement.

The dissemination of printed clinical guidelines or unbiased drug information alone is not sufficient to cause measurable improvements in behaviour. However, dissemination of guidelines through staff training, user involvement guidelines or audits and feedback has resulted in improved drug use; each of these additional measures adding to the effect. Access to comparative, independent drug information is essential in the preparation of these important tools.

Problem-based training in rational drug use and WHO's *Guide to Good Prescribing*⁶ can be used to train medical students and have been shown to be effective in improving therapeutic decisions. Medical students can easily be taught to critically appraise promotional material (see the example from Indonesia on page 23).

It is possible to achieve major improvements in regional or national standards of

care. The Uganda and Zimbabwe Essential Drugs Programmes are good examples of how the use of medicines in national essential drugs programmes can be improved. Regular drug use surveys using indicators should be included in national programmes.

5) Improving Patients' Use of Medicines

This review examined studies which focused on the drug use of individual patients undergoing treatment rather than on consumers in general. The pharmaceutical industry, health care providers and pharmacists all play an important role in providing information on the use of pharmaceuticals, and are often responsible for misuse. Combining the data on poor prescription with the data on poor consumption it is obvious that only a small proportion of those with treatable illnesses take medications appropriately. Strategies to improve the use of drugs have to aim both at the health professionals and at those using the drugs.

The concept of compliance has been developed to describe whether a patient takes a drug according to the advice they receive from a health care professional. But compliance should not be seen as an end in itself, compliance is only beneficial if it leads to improved health or reduced suffering. Also the term compliance is not always helpful because it implies a passive role on the part of the patient rather than a partnership between the patient and the prescriber or dispenser. Sometimes it is forgotten that there are circumstances in which a patient does better not to comply with the advice of the professional. When unnecessary or inappropriate drugs are prescribed, if a patient has to choose between buying drugs or buying food, or if a patient experiences unpleasant side effects, the best course may be not to take the drug as prescribed.

Twenty-nine studies were identified which reported on the results of interventions aimed at improving patient use of medicines. Of these only 10 used a design which met the methodological criteria defined. Even so the findings of all studies were reviewed because it was judged that the findings might be suggestive, even if they could not be seen as providing definite evidence. Most of the studies focused on one of the following: compliance with antituberculosis treatment, the treatment of diarrhoea, high blood pressure, malaria and ARI.

Different strategies were used to improve medicine use. These included:

- ◆ changes in the provision of services;
- ◆ educational strategies;
- ◆ increased supervision;
- ◆ improved presentation and packaging;
- ◆ mass media campaigns.

Most studies used more than one strategy simultaneously. Different illnesses and treatment regimes seemed to call for different strategies. For example, most studies dealing with tuberculosis included the use of increased supervision, most studies dealing with malaria attempted to change the appearance and presentation of the pill.

The studies which looked at therapy for tuberculosis found that increased supervision was important in ensuring that medication was taken and treatment completed. The supervision did not have to be provided by a health professional but could be provided by someone in the community.

The studies which focused on oral rehydration therapy (ORT) suggested that the use of ORT can be improved. They also suggested that while person-to-person methods worked best it did not seem to make much difference whether the

teaching was individual or in groups. Strategies which combined measures to improve prescribing together with better information for patients provided interesting results.

Strategies to improve the use of malaria chemoprophylaxis for pregnant women were judged to be cost-effective. Two of the interventions reported managed to improve use by improving the taste and appearance of the pill. In the case of high blood pressure strategies were successful in getting patients to the clinic for follow up but it was not clear that this resulted in better treatment or better health outcomes.

The therapeutic importance of antibiotics, the problem of resistance and the considerable spending on antibiotics are three compelling reasons to address issues of poor prescribing and poor use of antibiotics.

Lessons learnt

There was clear evidence that knowledge and understanding improves medicine use during short-term treatment regimes. It cannot be said that knowledge ensures appropriate use, but knowledge and understanding of treatment are certainly important factors in whether drugs are used well. Training prescribers and dispensers to improve the way in which they communicate with patients is important.

It was clear that different problems and different types of illnesses and therapies required different strategies to ensure appropriate use. Family members and members of the community can supervise and teach people to take their medicines appropriately. Pharmacists have an important role to play and are often under used.

Discussion at the conference stressed the importance of making drug information available and understandable so that people know what drugs they are taking, why they should be taken and how they should be taken. Through provider training and increased information, education and communication it should be possible to develop a balanced relationship between a well trained prescriber and an empowered consumer, jointly making a therapeutic decision.

6) Improving Consumers' Use of Medicines

In many developing countries over 80% of all drugs are purchased by people for themselves or family members without a prescription. Even if drugs are obtained after consultation with a health worker, the way in which they are used will depend on the understanding and decision of the individual consumer. This means that an understanding of people's attitudes to medicines is fundamental to attempts to improve use.

The review examined four broad strategies used to improve consumer use of medicines:

- Targeted training, including strategies to involve members of community groups through an empowerment approach, or through community level health workers or drug sellers;
- Social marketing programmes;
- Networking, advocacy and campaigning;
- Public education.

A wide range of studies, evaluations and articles was reviewed. But although much has been written about consumer drug use there are few studies which match the agreed criteria for the reviews. Most of the studies which did match these criteria fall into the first category of targeted training, and there are few studies which examine

the impact of social marketing, campaigning or public education. Much of the material about public education strategies came from the Action Programme on Essential Drugs, global survey of public education activities⁷.

Targeted training

The studies show that persuasive health education, when well conducted, is effective and can lead to improved drug use. The case management studies found that it is possible to train community-based health workers (members of the community) to recognise the signs and symptoms of target conditions, and to improve case management, including better use of drugs. Pharmacists and drug sellers were successfully trained using interactive techniques to increase their management of diarrhoea. Collaborative action studies deal with the problem of drug use in general and involve communities in the description, assessment, improvement and evaluation of drug use and existing services in their area. One study from Pakistan showed how the community, in collaboration with research partners, built on their own findings to design interventions⁸.

Box 10

In Thailand an intervention was developed which involved collaboration between the district hospital pharmacist, village drug cooperatives, village health volunteers and local store owners. They developed incentives to make the procurement of essential household drugs easier and more profitable and to reduce the use of dangerous prepacked mixtures of drugs known as ya-chud⁹.

Social marketing

Social marketing has not been widely used as a strategy to promote general rational drug use messages although it has been used in the specific areas of contraception, ARI and diarrhoea. The aim of social marketing is to use commercial marketing approaches to change behaviour. It is usually associated with mass media promotions.

Social marketing can be effective but tends to be very expensive and unless the campaign is sustained the impact tends to be short-term. Messages have to be simple and direct, and social marketing is best used to support other, more interpersonal, forms of information and education. Social marketing builds on the concept of selling products and this product orientation may not be appropriate for rational drug use messages. The programmes have often involved brand name promotions, and this can undermine the credibility and independence of health educators.

Advocacy and campaigning

Little has been published about the impact of the groups whose main strategy is to change drug use through advocacy and mobilisation for policy change. Health Action International (HAI) is one example of an international cooperative network which supports a more rational use of drugs through information exchange, training, advocacy and campaigns. Action for Rational Drugs in Asia (ARDA) is a regional network with similar aims. External evaluations of HAI and ARDA have been carried out, but these are largely descriptive evaluations with qualitative assessments of organizational performance

and output, rather than assessments of impact on drug use.

These networks and others aim to influence decision makers and sometimes the public, through argument, briefing documents, exposure of malpractice and other forms of communication. They have been successful in focusing attention on the essential drugs concept and in keeping drug issues high on the political agenda. They aim to achieve policy change more than individual behaviour change, although the long-term goal is to improve health through more appropriate use of medicines. The impact of this work is difficult to measure, separating cause and effect is difficult and setting an appropriate time frame is a problem. The final outcome, "improved drug use", is often many steps removed from the political advocacy work or campaigns.

Public education

Public education interventions in rational drug use are taking place in many countries but often they are not documented. The Action Programme on Essential Drugs carried out a survey which gives valuable information on these activities⁷. Throughout 1995 national and regional consumer and development groups helped to identify projects, and solicit information through a structured questionnaire. Information was gathered on project planning and implementation, target groups and expected changes, materials and channels of communication, evaluation of reach and impact, funding, and facilitating and constraining factors.

Most of the activities were being carried out by NGOs. The data showed that in developing countries mass media were the most popular channel of communication, followed by workshops and the use of printed materials. Many projects used a mixed approach. The main problems encountered were lack of financial and human resources, weak external collaboration and support, poor coordination, opposition from vested interests, and an unsupportive infrastructure. Support from other organizations, stable personnel and strong planning were factors which were seen as contributing to success.

The analysis of the survey draws attention to the fact that few of the activities are written up and reported, and it is stressed that this makes it difficult to enable better funding and also makes it hard for groups involved to learn from each other. Respondents to the survey stressed the importance of education for rational drug use, and stated that there was a need for better collaboration with professional partners and with the target group, better planning and clearer objectives. There was also a recognition of the fact that behaviour change is difficult and long-range.

Gaps in our understanding

Both the review and discussion at the conference stressed the need to understand the cultural context in which interventions were carried out. A successful intervention in one country or region may be highly unsuitable in another. When designing studies or interventions this should not be underestimated. The contradiction between different rationalities and how to bridge them is the challenge for improving drug use in the community. The role of drug marketing and promotion on drug use is powerful but not well understood. There is a general consensus that promotion exerts a powerful influence on both prescribing and consumer use. However, it would be useful to have evidence which showed the extent and mechanisms of this influence.

Lessons learnt

Discussion at the conference stressed that effective strategies are needed to encourage the growth of a strong consumer movement and underlined a fundamental need to evaluate the impact of community-based interventions, so that more can be learnt about the process and necessary changes made. Human and financial resources should be allocated to public education activities aimed at improving consumer use of medicines. Consumer education initiatives will only work if they are developed in cooperation with those involved, and are relevant to their needs and beliefs.

Box 11

The future: eight ways to promote improvement in consumer use of medicines

- ◆ Create a supportive climate for work in this area. Policy makers and professionals should understand how important it is.
- ◆ Allocate adequate resources.
- ◆ Link research to action. Translate research into appropriate and implemented policies.
- ◆ Invest in training in planning, implementation and evaluation.
- ◆ Understand and invest in appropriate methods. Help people to do this work in a way which does not invalidate their approaches but which strengthens and improves them.
- ◆ Accept diversity in approaches.
- ◆ Respect people. They should be involved, supported, enabled and listened to. The search for evidence should fit into the context in which people live.
- ◆ Strengthen collaboration between groups.

The following review papers and case studies were presented in plenary at the conference (only presenters, not co-authors, are named):

1. Improving use of medicines by health providers in primary care. Dr D. Ross-Degnan, Harvard Medical School, Dr R. Laing, Boston University School of Public Health, USA.
Case Study: Impact of an educational strategy for physicians to improve treatment practices of common diseases. Dr H. Guiscafne, Division of Research on Epidemiology and Health Services, Instituto Mexicano del Seguro Social, Mexico.
2. Improving the use of medicines by patients receiving treatment. Dr N. Homedes, School of Public Health, Professor A. Ugalde, Department of Sociology, University of Texas, USA.
Case Study: Global survey on public education activities/interventions in rational drug use. Ms D. Fresle, WHO, Action Programme on Essential Drugs.
3. Improving use of medicines by consumers in the community. Ms M. Murray, Hodge Murray Hodge Ltd, Australia, Dr M. Tan, Health Action International Network, Philippines.
4. Improving drug use in hospitals. Dr R. Laing, Boston University School of Public Health, USA.
5. Impact of pharmaceutical policies and regulations on use of medicines. Dr S. Ratanawijitrasin, Faculty of Pharmaceutical Sciences, Chulalongkorn University, Thailand.
Case Study: New paradigms for evaluating economic and societal benefits of medicines. Dr S. Finkelstein, Program on the Pharmaceutical Industry, Massachusetts Institute of Technology, USA.
6. Impacts of economic factors on use of medicines. Dr C. Cederlof, Karolinska Institutet, Sweden, Dr J. Quick, WHO, Action Programme on Essential Drugs.

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OUTCOMES OF ICIUM

ICIUM provided a forum for a comprehensive review of work to improve the use of medicines. But the conference did much more than review and analyse. It also made a wide range of recommendations and identified clear needs. The detailed conference recommendations have been summed up for *Monitor* readers under the following broad headings (REACT), which can help in planning and prioritising future work:

Research. Areas were identified which need investigating. Methodological limitations and problems were identified and prioritised.

Evaluation. It was stressed that it was necessary to evaluate and, if necessary, modify strategies to improve the use of medicines. New ways of evaluating and understanding complex processes need to be developed.

Action. Research and review are not enough to achieve change. Political will and action are required to address problems in this area.

Collaboration. Involving and empowering consumers are essential, collaboration with all stakeholders is essential in implementation.

Tools and training. Participatory training and the development of appropriate tools and guidelines are a priority.

Research. Many of those active in the area of drug use research participated at ICIUM, and future directions for research were among the main outcomes of the conference. A detailed research agenda was identified which, as it is carried out, will fill many of the gaps in our understanding of drug use. Attention was drawn to the fact that, whilst there have been many studies at the level of primary care, these have tended to concentrate on a limited range of disease conditions. Other levels of care have received much less attention. Also most research has looked at the public not the private sector yet the latter is the main source of health care and medicinal drugs in many countries, and with the present trend towards structural adjustment has an expanding role. The role of policy and regulation is also not well understood and we know little about the impact of economic influences.

Inadequacies in the methodologies used by many of the studies were highlighted and it was concluded that with stronger study designs much better evidence could be



Talking health in China on World Health Day. A lot more communication amongst all involved in health care will be necessary for these children to grow up in a world in which drugs are used rationally

collected. In particular the importance of collecting baseline data and the usefulness of time-series studies were stressed. At the same time many of the discussions focused on the need to develop qualitative and mixed research methods, to give a deeper understanding of the complex areas of drug use and drug policy. (As part of a commitment to follow up from the conference, a consortium of organizations will support research in selected areas identified at ICIUM. For more details see below).

Evaluation. Many interventions to improve rational drug use have never been evaluated. Both at the level of national policy and at the level of consumer education much is done which is not evaluated and often not even reported. This means that much experience is lost, that people are unable to learn from the successes or mistakes of others, and that often we do not know whether an intervention was effective, had no effect, or whether it had unintended or adverse effects. Useful approaches to the evaluation of essential drugs programmes have been developed and need to be more widely used. Developing appropriate indicators for evaluation and monitoring in other areas is important. Methods to evaluate the impact of different financing mechanisms would help policy makers in difficult choices. Encouraging researchers and other actors to evaluate and report their activities and exchange experiences is essential.

Action. Scientific research and evidence may be essential but they are not sufficient to achieve change. If we are concerned not just to advance knowledge but to improve drug use and health then we have to make the move from research into policy and implementation, from study into action. The essential drugs concept is evidence-based, cost-effective, tried and tested. However, it has not been universally adopted because its implications are political and the area of drug policy is a controversial one, with conflicting interests. The conference stressed that ideals, commitment and political will are needed to translate evidence into action.

Collaboration. Collaboration was identified as one of the keys to success. Collaboration between stakeholders and the support of active consumer groups were key to the success of drug policy interventions. Collaboration and information exchange between researchers, between team members in hospitals, between health professionals and consumers, and between private and commercial interests were all

identified as crucial to achieving change in the area of drug use.

Tools and training. There is evidence that essential drugs lists, formularies and standard treatment guidelines are very effective tools if they are properly developed and followed up. They should be developed through a participatory process. They should be evidence-based and should be developed with the aim of improving the quality of care not just to reduce costs. Activities which involve using them in training, in audit programmes and as a basis for feedback all add to their impact and acceptance. Training of health professionals should be problem oriented. Effective tools such as the *Guide to Good Prescribing*⁶ exist and can be adapted for use in different situations. But tools more appropriate to hospital settings need to be developed and adapted. Training and training materials for conducting and evaluating consumer education activities should be a priority, and should also be developed in a participatory process to ensure that they are relevant and appropriate to the communities in which they will be used.

CHALLENGES FOR THE FUTURE

The conference was inspiring and challenging and it provided a valuable opportunity for networking and for exchange of experiences and views. However, the success of ICIUM will be measured by how broadly its recommendations are translated into action, both in implementing successful strategies and in carrying out the priority research agenda to fill current gaps in experience. Dr Suwit Wibulpolprasert of the Thai Ministry of Public Health called upon participants to work together to pursue this agenda not only through "open windows of opportunity", like the development of Good Manufacturing Practice guidelines and educational activities to support them, but also through the more difficult terrain where their interests may conflict, the "forbidden windows," such as in implementing effective generic drug policies. Dr Alfredo Bengzon, former Secretary for Health in the Philippines, challenged researchers to become more active in the political process both to inform and motivate political leaders. He said that without active involvement even the best research would be of no value in improving people's health.

In his closing speech, Dr Hans

Hogerzeil, speaking for the Action Programme on Essential Drugs, stressed that the fundamental goal of the essential drugs concept is equity in health.

"Equity is a moral choice, based on concern for the poor and the disadvantaged. Although it needs the political means and a scientific basis, in essence it remains an idealistic choice with the vision of a better world. This conference has shown us that we can be self-confident when choosing for equity: we have a clear purpose in mind, we have the knowledge and experience, and we are not alone."

FOLLOW UP FROM ICIUM

Advancing the research agenda

A series of research priorities were identified during the conference, and a consortium of organizations has made a commitment to support work to follow up some of these priorities. This consortium includes the Applied Research on Child Health (ARCH) Project, the International Network for Rational Use of Drugs (INRUD), the Rational Pharmaceutical Management (RPM) Project and WHO's Action Programme on Essential Drugs. The sponsoring organizations are prepared to support research on interventions or policies to improve the use of medicines. Research proposals have already been solicited for a first phase of the follow up. The first phase will focus on improving professional practice in developing or transitional countries. Future phases will focus on other priority areas identified during ICIUM.

Anyone wishing for more information should contact the coordinating centre for the research initiative at the following address: Ms. Carolin Dudumian, ARCH Project, Harvard Institute for International Development, 1 Elliot Street, Cambridge, MA 02138, USA. Fax: (+1) 617 495 9706, e-mail: health@hiid.harvard.edu

ICIUM on the Net

At <http://www.who.ch/programmes/dap/icium/iciumpage.html> you will find conference programme details. The ICIUM site, which is still under construction, gives abstracts of participants' presentations, and by its completion in early 1998 the speeches and final papers will have been added. □

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Patients leaving a health centre in Nepal are questioned about quality of care, as part of a field trial of drug use indicators. The conference called for more research of this type to fill in the many gaps in our understanding of drug use

RATIONAL USE

Improving drug use in Africa: HAI's new initiative

➤ LISA HAYES*

THE problems caused by irrational drug use and lack of access to essential drugs remain a daily reality for millions of African consumers. Unaware of the best treatment or unable to buy it, many people end up spending their scarce resources to buy ineffective and expensive drugs. Such dilemmas and finding ways to address them provided the foundation for Health Action International's (HAI) Eastern Africa regional training workshop "Promoting the Rational Use of Drugs", held from 15–19 March 1997 in Nairobi, Kenya. The meeting launched HAI's new three-year project to improve consumers' and prescribers' use of drugs on the continent.

For five days, 35 participants from Eritrea, Kenya, Tanzania, Uganda and Zambia, together with members of the HAI-Europe staff, considered ways to promote the essential drugs concept and discussed many of the problems currently impeding rational drug use. The meeting aimed to encourage regional cooperation to promote rational use. Its participants included representatives from African health NGOs, academics, journalists, independent drug bulletins, consumer organizations, women's health associations, essential drugs projects and health educators.

THE ISSUES

While presenting a snapshot of the pharmaceutical situation within each of the represented countries, the participants emphasised a few common problems facing the region, including:

- ◆ **problems in implementing national drug policies:** As Rose Kinuka of the Ugandan Red Cross Society pointed out during the meeting, "The problem is not so much the lack of national drug policies as a lack of adherence to them. In a weak health care infrastructure, it is difficult to close down an unlicensed drug shop when an alternative health care service is not provided."
- ◆ **a shortage of trained, health professionals:** Many participants emphasised the small number of trained pharmacy and medical staff



Secondary school students from Kenya present a play promoting rational drug use during the HAI workshop

working in their countries. As most health professionals choose to work in urban areas, this leads to a vast underserving of those living in rural areas. Street vendors do a brisk business in providing health advice and drugs when other outlets are unavailable, too expensive or viewed as unapproachable.

- ◆ **inadequate consumer counselling on drugs:** The lack of professional health advisers leads many consumers to try and treat themselves when they become ill. Often this results in a misdiagnosis of the actual condition and/or an incorrect and ineffective drug treatment. In many of the countries represented injections remain the favourite method of treatment, regardless of the illness. Often health workers feel they will lose valuable customers unless they give in to the demand for what patients call "serious medicine", however inappropriate the injection may be.
- ◆ **low quality or inappropriate drug donations:** Low quality or inappropriate drug donations often bypass government distribution channels, as they are imported by local NGOs and distributed directly to consumers.
- ◆ **uncontrolled drug promotion:** The liberalisation of economic policies which has taken place over the last decade has made African markets ripe for advertising by multinational pharmaceutical companies. Many consumers are unable to distinguish between independent drug information and promotional claims, yet they have direct access to pharmaceutical drugs. Uncontrolled promotion leaves people open to unscrupulous or inappropriate drug marketing. It can result in them buying drugs which at best are useless for their condition or at worst endanger their health.
- ◆ **inadequate means to assess drug quality:** Drug smuggling across country borders remains a large problem in some African nations. Banned and

expired drugs find their way onto the market and into the hands of unknowing consumers. Costs also prevent many countries from setting up quality control laboratories to test pharmaceuticals before they are distributed for use.

CALL FOR STRICTER LEGISLATION AND ENFORCEMENT

Those attending the workshop called for cooperation among different sectors in order to improve rational drug use. Policy makers, community leaders and health professionals were all named as key participants in achieving this goal. Specifically, participants called for stricter



Participants from five Eastern African countries presented their national plans for action at the meeting

legislation to protect consumers from bad quality drugs and unethical drug promotion. The group agreed that government enforcement is also needed to ensure that consumers are not harmed by the drugs available. Participants discussed ways to set up national consumer education activities and awareness-raising campaigns to make information about drugs better known and understood by consumers and prescribers.

As part of the workshop, participants also drew up national action plans. These plans were developed to meet the specific needs of each country involved in the

meeting, focusing on priority groups and activities. Concrete plans have now been made to provide more independent drug information, to empower consumers with objective information about the drugs they use, and to find ways to influence national policy on drugs.

HAI'S NEW AFRICA PROJECT

The Nairobi training workshop was the first of three regional training sessions planned to take place in Africa. A second meeting is scheduled to be held in Southern Africa in early 1998. A final training workshop will take place in francophone Africa later next year. The

three regional workshops are just some of the highlights of the new project. In addition, the work will focus on identifying new contacts in Africa, establishing effective communication using electronic mail, organizing public awareness campaigns, carrying out research, providing regional representation, and producing newsletters and briefing papers on topics of interest to groups in the region. The project also plans to lay the groundwork for a regional HAI coordinating centre on the continent. HAI

plans to carry out the project's activities in close collaboration with other health, consumer and pharmaceuticals networks already active in Africa. □

* Lisa Hayes is Publications and Information Officer at HAI-Europe, Amsterdam.

To receive a copy of the Nairobi workshop report or more information about HAI's project in Africa, please contact HAI-Europe, Jacob van Lennepkade 334-T, 1053 NJ Amsterdam, the Netherlands. Tel: +31 20 683 3684, fax: +31 20 685 5002, e-mail: hai@hai.antenna.nl

French monitor prescribing

A recent report on the use of psychotropics in France showed that there was little data on which products were being prescribed by whom, for whom and why, as authorities did not monitor or evaluate doctors' prescribing decisions. As a result the Government has set up a Steering Committee to monitor the prescribing and consumption of medicines. The new Committee fits in with the Government's "medically-based" approach to curbing health care consumption, according to Committee member, Dr Bernard Avouac,

Head of the Transparency Commission. The Committee will also be required to provide information to the Drug Pricing Committee, with data on how and why medicines are prescribed, and whether certain medicines are medically justified. Committee members include experts in epidemiology, public health and pharmaceuticals, as well as representatives of national insurance agencies and mutual insurers. □

Source: Scrip No.2211, March 1997.

RATIONAL USE

Catching them young – the key to improving rational use

➤ M.V. NATU, M.M. DEODHAR
AND S.K. LEEKHA*

WHILE India's health care professionals increasingly accept the importance of rational drug use and its relevance to treatment at all levels, the issue has still not achieved the prominence it should. The main reasons for this are lack of awareness in the medical community, lack of enthusiasm and translation of ideas into actions, and insufficient political interest and commitment.

We felt that the general ignorance of the subject was due to the absence of rational use issues in the medical curriculum. So five years ago the Department of Pharmacology at the Christian Medical College, Ludhiana, initiated teaching on rational use of drugs and the basics of formulating essential drugs lists for our undergraduate medical students, right at the beginning of their pharmacology course. In this way they come to realise the importance of the subject at the start of their student life and can build on their knowledge in the following years.

Involving the students

Our aim is that by the end of the course students should be able to express the essential drugs concept in their own words and understand the importance of the

rational use of drugs. The subject is introduced in a lecture, and we have also prepared handouts containing simple and relevant information, including the course objectives. From the beginning we have involved students in a very practical way. Among the tasks they are set is to visit a slum area and then prepare a list of 10 drugs appropriate for a small dispensary in such an area. We ask them to find out from hospital clinicians whether they prescribe by generic or trade names and whether they only prescribe drugs from the Hospital Formulary or not, and why. Our students also interview two senior students to see if they use any medicines without physician's advice and, if so, the names of the drugs and the reasons for taking them.

One week later small group discussions are held to review these activities, with eight to 10 students, and a teacher as a facilitator. The session on a drugs list for a small dispensary always stimulates lively debate. This is especially the case when disagreement over drug choices leads to very useful discussion on alternative drugs, and on inclusion criteria for a particular drug or class of drugs.

In their interaction with clinicians in our hospital, students find that prescriptions are usually based on the Hospital Formulary, although in some cases newer/alternative drugs which may prove more

beneficial are used. Most senior students' drug consumption is usually restricted to use of analgesics or antipyretics, but in some cases includes antibiotics and sedatives. Again these exercises prompt debate on wider rational use issues. Overall, a wealth of information seems to be amassed by the end of each session, all resulting from the students' own active participation.

To our knowledge neither teaching nor discussion of rational drug use and essential drugs lists takes place in most other medical colleges in India. We would therefore like to share our teaching ideas with all such colleges. We believe that the topic can easily be incorporated in the pharmacology course syllabus for third-year students. Since the rational use of drugs is a topic of great community importance, we feel that its inclusion in the curriculum will not be a problem for college authorities.

In conclusion we would like to re-emphasise that young learners of *today* will be the teachers of *tomorrow* – catch them young! □

* M.V. Natu is Professor and Head, Department of Pharmacology, M.M. Deodhar is Professor of Pharmacology (Retired) and S.K. Leekha, Resident, Department of Pharmacology, Christian Medical College, Ludhiana – 141008, Punjab, India.

Colombia adds rational drug use to curriculum

SINCE 1990 DAP and the WHO Regional Office for the Eastern Mediterranean have held a series of national and sub-regional workshops for key staff at medical and pharmacy schools, to promote the inclusion of the essential drugs concept in the undergraduate curricula. Now the first meeting of this kind has taken place in Latin America. Held in Cali, Colombia, in March 1997, the national workshop was attended by representatives from 18 medical schools, Health Ministry and local government officials. Two DAP staff acted as facilitators. The workshop came at an opportune moment, as a national review of medical curricula is to take place.

Main recommendations from the workshop included: the promotion of evidence-based medicine and problem-based pharmacotherapy teaching, and the setting up of a national network to promote teaching of clinical pharmacology and therapeutics. The recommendations have been shared with all medical schools in Colombia, and the country will soon join the growing list of those introducing rational drug use to their medical curricula. □

Moves to strengthen pharmacy curricula

FOLLOWING extensive work to promote the teaching of rational prescribing in undergraduate medical curricula, the Action Programme on Essential Drugs has started a similar project targeting pharmacy curricula. Many schools of pharmacy focus on teaching basic chemistry, drug compounding and production. But this knowledge is hardly used by most pharmacists. In contrast, many widely

relevant subjects such as pharmacology, pharmacy management, communications skills, community pharmacy, clinical pharmacy, and drugs and therapeutics committees, receive insufficient coverage.

As a first step, two regional consultations took place in Nyanga (Zimbabwe) and Beirut (Lebanon), attended by some 50 heads of pharmacy schools, professors and specialists in pharmacy education and public health. The most important outcome of the Nyanga meeting was a complete list of core skills of a modern pharmacist, which can serve to develop a need-based curriculum. The Beirut meeting reviewed this list and developed a core curriculum. Two other regional consultations are planned, probably in South-East Asia and francophone Africa. Both the list of core skills and the core curriculum (available from DAP) can be used for review and change in undergraduate pharmacy curricula. □



A pharmacy in Peru. The move to change the pharmacy curricula reflects the evolving role of the profession

Netherlands: inventory of RUD groups

THE Dutch Foundation for Rational Drug Use has published an inventory of projects* improving the use of medicines by prescribers, dispensers and consumers in the Netherlands. The Foundation, an independent body subsidised by the Ministry of Health, has listed approximately 100 different projects and programmes by local, regional and national organization.

To the Foundation's surprise hardly any cooperation existed between the different organizations, which all have their own target group. It discovered that projects are unknown, completed projects "vanish" without proper evaluation of their impact and interesting data are lost because they are not recorded or disseminated.

The inventory enables organizations wishing to start or develop an activity to check what others are doing the same, and where. They can access expertise, exchange experience and evaluations, learn about the latest developments, the impact of programmes and – not least – the possible problems. Doctors faced with specific drug use problems can check the inventory to access information on projects in their region. Examples include programmes to reduce patient dependence on sleeping tablets, drug information services for elderly patients, translation services for immigrant workers and continuing drug education projects for general practitioners. The publication also lists ongoing research projects.

The inventory makes a valuable contribution to promoting the rational use of drugs in the Netherlands. It will facilitate cooperation between various groups, enabling them to join forces, work more effectively, and improve the dissemination of information about how consumers, patients and health workers can use drugs in a more responsible way. □

For further information contact: Drs G.A.L.Kocken, FTO adviesgroep, Bosscheweg 57, 5056KA Berkel-Enschot, the Netherlands.

* Available in Dutch only.



RESEARCH

Suntik, ya? Investigating popular demand for injections in Indonesia and Uganda

> ANITA HARDON AND
ANNELOES VAN STAA*

In health centres in Central Java, Indonesia, a patient's treatment basically consists of administering an injection and prescribing several pills. Consultations, usually with nurses, are often very short and end with the rhetorical question: "Suntik, ya?" ("Injection, yes?"). As a result about 80–90% of patients leave the clinic with a new fluid in their body¹. Indonesians are by no means alone in their desire for injections, in many countries health workers are confronted with patients who prefer them to oral medications. The historical background to this popularity may be the spectacular cures achieved with injections, such as quinine to treat malaria and penicillin to treat yaws. However, apart from their reputed efficacy, economic factors may also underlie widespread injection use. Healers can demand a higher fee for administering an injection than for prescribing tablets.

Inessential injections and injection overuse have prompted increasing concern among international agencies, such as WHO, national health officials and policy makers, and health workers in the field. From a health perspective administering injections without adequate medical knowledge or proper sterilisation procedures leads to the risk of transmitting serious diseases, such as hepatitis, poliomyelitis and possibly AIDS. In addition, the drug that is injected is often medically unnecessary, and potentially dangerous. From an economic viewpoint, the irrational use of injections imposes an additional burden on limited household and health centre budgets, particularly in Africa with its continuing economic crises.

QUESTIONS TO BE ANSWERED

In many cultures the belief in injections as a very powerful method of restoring or maintaining health is shared by providers and consumers alike. The problem of injection use seems to be so complex that it cannot be solved by training alone – knowledge of the potential risks of injections often does not result in change of practice. Essential drugs programmes in developing countries aim to reduce both the overuse and non essential use of injections. To succeed they need to know: who is injecting, how often and for what purposes; if injections are given without medical justification; why they are the preferred route of treatment; and whether they are administered hygienically.

Acknowledging this, in 1990 the Action Programme on Essential Drugs in consultation with WHO's Expanded Programme on Immunization and the Global Programme on AIDS, initiated a research project in Indonesia, Senegal and Uganda, where the misuse of injections was reportedly a problem. The research focused on two, largely unanswered, questions: *what is the extent of injection use?* and *why are injections so popular?* To answer the last question, the causal and contextual

factors behind this demand needed to be explored, necessitating anthropological research methods, including participant observation, in-depth interviewing and focus group discussions. At the same time, quantitative data on the actual use of injections at both household and health service levels were needed, in order to explore the extent of the problem and the indications for which injections were used, and also to identify the most important sources of injections. This required epidemiological research methods, including household surveys and interviews with providers and users of injections. The development of simple and rapid methods to estimate the prevalence of injection use was one important objective in the initiation of the research.

UNJUSTIFIED, UNSAFE AND UNHYGIENIC INJECTIONS

A recently published DAP report² presents the results and recommendations from field studies in Indonesia and Uganda. In both countries, the great popularity of injections was confirmed: injection use was found to be highly prevalent both at the household level and

in health facilities. The results further indicate that this prevalence of injection use cannot be biomedically justified and that injections are often provided in an unsafe, unhygienic way.

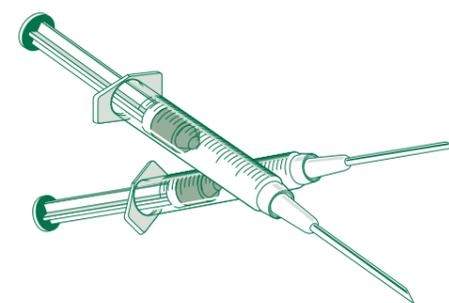
Qualitative and quantitative methods were used to collect data from users and providers. Household surveys were carried out in two regions of each country, covering a total of 360 households in each region. Injection use in the previous two weeks was recorded. Preferences for injection therapy were investigated through in-depth interviews and focus group discussions. Provider-oriented methods included the use of open-ended questionnaires, a review of prescriptions, patient exit interviews and observations in provider facilities, such as government and private medical clinics and various 'non-formal' sources of injections. The two main strengths of this research project's methodology are the combination of qualitative and quantitative data collection methods; and the flexible research design which allowed for modifications according to local conditions. At the same time, formulation of common injection practices indicators helped to provide cross-country comparable data.

CHILDREN AT RISK

The *prevalence of injection use*, which was defined as the percentage of households in the surveys receiving one or more injections in the previous two weeks, was found to be high in both countries – from around four in 10 households in Indonesia, to three in 10 in Uganda. There were no significant differences between the injection rates of the urban, suburban and rural households in both countries, even though accessibility to modern health services varied between locations. The great majority of the injections reported in the two-week recall

period had been given for therapeutic reasons (80–90%). Intravenous drips are not very common and immunizations are infrequently reported. In Indonesia it was found that the percentage of children under five receiving an injection was twice as high as the percentage for the entire research population.

There is a marked difference between the two countries with respect to the *source of the injections* received



in the households. In Indonesia the majority originate from the public sector, with private practices of doctors and nurses (who work in the public sector as well) also popular. In contrast, in Uganda, private medical practices are far more popular than Government health facilities as injection providers. Most striking, however, is that many injections are given by non formal providers or at home by family members. This reflects the trend of informalisation in Uganda, where public facilities are often mistrusted and held responsible for the spread of the AIDS epidemic.

Injection use rates at public health facilities are fairly high in both countries. In Uganda an injection is given in between six to seven out of 10 treatments. In Indonesia of every 10 patients treated in one of the study areas, seven received an injection. In the second region the mean injection rate is even higher: almost nine out of 10 visits here end with one or more injections being given.

In both countries high rates of injection use in uncomplicated, non severe and self-limiting illnesses are found, indicating *medical inappropriateness of injection use*. In Uganda fever is most often treated with injections – especially when accompanied by other symptoms. Over 95% of all injections prescribed are chloroquine, penicillin procaine fortified (PPF) and crystalline penicillin. A very popular combination consists of PPF with chloroquine. In Indonesia, injections are given in over half the recorded illness cases in the households. The highest injection rates are found in the treatment of skin diseases (approximately 60%). The most commonly used injectables include antibiotics, vitamins, analgesics and antihistamines. Particularly striking is the



Patients watch as a nurse carries out sterilisation procedures. In Uganda the trend for patients to use their own injection equipment has led to increased concern about hygiene levels

cont'd on pg. 16

Suntik, ya?... cont'd from pg. 15

popularity of oxytetracycline for the treatment of all recorded illnesses.

HYGIENIC APPROPRIATENESS OF INJECTION ADMINISTRATION

The research demonstrates that injections in both countries are often unsafe as the minimum hygienic requirements are not being met. In Indonesia the majority of providers interviewed used disposable syringes. However, most disposables are not discarded immediately after use but are reused after 'sterilising'. In Uganda the majority of households keep injection equipment at home, as a consequence of both the popular concern about AIDS and the distribution of injection equipment to the users by private and non formal providers. In health facilities it was observed that around 60% of patients bring along their own syringe and needle, making it difficult to meet optimum hygiene standards. At the same time, a high percentage of provider facilities in both countries do not meet the

required minimum standards of hygiene at each stage of injection administration. A higher level of training for health workers was not related to the provision of safer injections. Many Ugandan households are familiar with complications due to injections, particularly injection abscesses. Popular explanations of the causes of such complications do not place the blame on lack of hygiene or inappropriate injectable solutions, however, but rather on the personal qualities ('bad hand') of the provider.

The enormous *popularity of injection therapy* was confirmed in both countries. If self-medication with oral therapy brings no relief, or when a fast cure is desired, patients tend to solicit providers for an injection. This preference is guided by local ideas and beliefs on illness and concepts of efficacy. It is further strengthened by the economic interests of private providers. In Indonesia, users stated that it is "customary" to receive injections in health facilities. Customers have little say over this routine treatment. When the providers are asked why they give injections, they usually claim that it is because of patient demand. This vicious circle

(health workers give injections because they think patients expect them; patients want injections because health workers give them) and the lack of communication between both parties serves to continue the practice of routine administration of injections. The research confirms that communication between health workers and patients is unsatisfactory. Over half the patients had not received any explanation from the health worker about their treatment.

TACKLING A COMPLEX PROBLEM

The research teams recommend a number of managerial, educational and regulatory interventions. However, such interventions will only be successful if they consider the underlying reasons for injection misuse both for providers and for users. For example, while training of health providers is necessary and worthwhile, it does not ensure correct use of injections and drugs in general. Also, in many contexts it is no longer possible to eliminate injections from the range of

treatments available. Such intervention would be met with both incomprehension and opposition from providers and patients. Therefore, any policy to be adopted must be based upon detailed research of the cultural meaning of injections, their place in medical practices and their influence upon human relations. □

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NEWSDESK**USP Conference on Children and Medicines**

PARTICIPANTS at an open conference sponsored by the United States Pharmacopeia (USP) fully affirmed the conference subtitle: "Information isn't just for grownups." Over 100 participants (mainly US-based), representing a wide variety of disciplines met in Reston, Virginia, from 29 September – 1 October 1996. They included members of USP's volunteer panels whose work most directly affects

medicine use by children: *Pediatrics, Consumer Interest and Health Education, and the Ad Hoc Panel on Children and Medicines* (see box).

The overall goals of the Conference were to answer two questions: What do children need to know before they become responsible for taking medicines? What are the best ways to inform and educate children about medicines?

Key observations from the Conference were that:

- children learn about medicines and develop beliefs, attitudes, and expectations about medicines almost daily in the "school of experience", such as through observing family members, using medicines themselves, and the media;
- children, especially those with chronic illnesses, have more autonomy in using medicines than most adults recognise;
- school health education programmes, where they exist, focus on preventing poisoning in young children and substance abuse by older children; rarely do any include information about medicines and their use;
- health professionals seldom communicate directly with children when prescribing or dispensing medicines to them, nor are children provided with written information about their medicines;
- children want to know more about medicines.

As with all USP open conferences, participants reviewed a pre-conference compilation of key articles, considered presented papers, and then met in



Top: A clear message from a 10-year old who took part in a 10-country study, *Children, Medicines and Culture*. During home interviews children were asked to draw themselves the last time they were ill

Above: At the USP Conference Anna Marie Lund, a 10-year old from San Francisco, presents her poster highlighting what she feels are the most important things children want to know about medicines

Photo: USP

USP Ad Hoc Panel on Children and Medicines

The Panel was established in 1995 in line with USP's mandate to promote public health by disseminating authoritative information on the use of medicines by health care providers, patients and consumers. Its goal is to develop guidelines for what children should know and how they could learn about medicines. In addition to planning the conference, the Panel has held focus groups with schoolchildren to learn what they want to know about medicines. It is producing a manual of criteria for evaluating or developing children's medicine education programmes and materials, and is developing drug information leaflets for children. The Panel also collaborates with health professionals in other countries who are interested in educating children about medicines.

NEWSDESK

Trade in pharmaceuticals: is legislation effective?

NATIONAL supply agencies, government bodies, pharmacists and consumers have to choose products in a growing and complex drug market. To make good choices they need clear and objective information about drugs, their origin and any legislation that covers the trade in these drugs. A recent publication, *Les échanges de Médicaments entre pays européens et pays en développement: efficacité des systèmes de régulation, problèmes et perspectives*, (The Drug Trade Between European and Developing Countries: The Regulatory Systems' Efficacy, Problems and Perspectives), reports on a study which examined the effectiveness of export legislation in 17 European countries (including the EU countries, Norway and Switzerland). It also analysed the regulatory aspects of the drug market in 17 developing countries, particularly in francophone Africa. The study was carried out in 1995 by the Paris-based groups, ReMeD (Réseau Médicaments et Développement) and PIMED (Pour une Information médicale éthique et le Développement), with Wemos, a Dutch NGO. The authors identify some of the strengths and weaknesses found in import and export legislation. They advocate greater transparency and new measures to better ensure the quality of drugs exported from Europe, still the main source of drugs for developing countries.

IMPORTING COUNTRIES MUST BE VIGILANT

The quality of imported products can only be assured if there is well defined legislation listing conditions related to product registration, and an effective authority to evaluate, register and control drugs. In recent years most developing countries have adopted legislation on drug registration, the basis for a system that controls the distribution, and particularly the import of drugs. In theory all countries in the study demand that all drugs distributed within their territory are registered, yet for numerous reasons (understaffing, lack of coordination of public agencies, existence of a parallel market) unlicensed products are available on local markets. Some countries, such as Chad, Côte d'Ivoire and Mali, have chosen to legalise the entry of drugs that cannot be controlled according to local standards. In other countries where normal procedures require the licensing of all imported products, the procedure is often waived.

Checking a drug's licensing status in the country of origin is an inexpensive way to take advantage of work done by other authorities. Although most



Zimbabwe's Regional Drug Quality Control Laboratory. The study reinforces the message that assuring the quality of imported drugs is vital in developing countries

countries ask for a certificate in the country of origin, the authors report that there is a great deal of confusion over the type of documentation requested. This confusion extends to the use of the WHO Certification Scheme. The Scheme provides information about licensing status and manufacturing conditions but it is used in many different ways. For example, major European exporters like France and Germany have insisted on issuing their own type of certificates, instead of using the format recommended by WHO. This has caused considerable confusion among importing countries. The situation is not uniform on the import side either, however. While certain countries

demand a WHO-type certificate, such as Algeria, Burkina Faso, Madagascar and Tunisia, others do not make this a prerequisite for registration, for example, Côte d'Ivoire, Kenya, Senegal and Zimbabwe.

As international trade is increasingly deregulated there is growing competition between drug suppliers. The authors argue that this contributes to the availability of substandard drugs, trade in products with a negative risk/benefit ratio and the use of double standards in drug information. They conclude that many aspects of the trade in pharmaceuticals are not covered by any legislation, and address their publication particularly to drug regulatory authorities and consumer organizations in Europe and Africa which are working to improve the situation. □

Copies of *Les échanges de Médicaments entre pays européens et pays en développement: efficacité des systèmes de régulation, problèmes et perspectives* are available, in French only, from: ReMeD, 7 rue du Fer à Moulin, Paris, France. Price: Fr.fr.50 plus postage. For an English language summary contact: HAI-Europe, Jacob van Lennepkade 334T, 1053 NJ Amsterdam, the Netherlands.

CALL FOR TIGHTER CONTROLS

Drug legislation in the European Union includes a number of provisions involving exports. For example, a pharmaceutical product destined for export can only be produced in an establishment with a manufacturing licence, and all countries have to participate in the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. In addition, all of the bans, suspensions and/or withdrawals related to a drug on the national level have to be declared to WHO, so it can distribute this information. Yet the study highlights 12 loopholes in the law which could make it easier for substandard drugs to be sent to developing countries. For example, 10 countries studied had no export restrictions on drugs withdrawn from the market and 12 placed no restrictions on export when they refused to license a drug. The authors argue that importing countries need clear and detailed information on the quality of drugs exported from Europe, and on any restrictions, to make informed decisions about drug regulation in their own countries.

Working group on drug reimbursement

ACCCESS to essential drugs and the need for revision of current drug reimbursement systems are becoming a top priority for several Newly Independent States. An inter-agency roundtable to discuss these issues was held in March 1997, in Moscow, under the auspices of the Ministry of Health of the Russian Federation and the WHO Regional Office for Europe's Pharmaceuticals Programme. The meeting, which brought together concerned ministries, the Pharmaceutical Association and oblast level health authorities, led to the formation of a working group to develop a proposal for a new drug reimbursement system. The group has met several times and will continue its work during the coming months.

In the meantime, Georgia's Ministry of Health is launching a pilot project to introduce a new drug reimbursement system in Kutaisi Region under the framework of the ongoing project with the WHO Regional Office. □

Launch of pharmacy newsletter

HEALTH workers in developing countries often lack information on drug management and rational use. To address this problem a quarterly newsletter, *Practical Pharmacy*, was launched in April 1996, with support from the Action Programme on Essential Drugs and ECHO International. The newsletter aims to ensure the safe and rational use of drugs worldwide by increasing knowledge and understanding of drug management and supply, and improving work practices. It provides easy-to-read information on basic aspects and skills of pharmacy work and will be a useful resource for training activities. *Practical Pharmacy* is written for individual health workers of all levels who may have no specific pharmacy qualifications.

To date the newsletter has included features on drug stability, problems with expired drugs, stock control, drug donations, drug interactions, the use of disinfectants and information about new books. Readers can look forward to future issues on: drugs in pregnancy, rational prescribing, traditional medicines, good manufacturing guidelines and drug advertising. □

Available, free of charge, from: G. Stock, Heatherlands, Lydford, Okehampton, Devon, EX20 4AU, UK. E-mail: G.F.Stock@bristol.ac.uk



NEWSDESK

New WHO group to combat unsafe injections

UNSAFE use of injections causes severe health problems worldwide. WHO has therefore created an informal working group to address the issue and to better coordinate WHO activities in this field. Currently DAP, the Division of Emerging and other Communicable Diseases Surveillance and Control, and the Expanded Programme on Immunization are the programmes most involved, although other programmes are contributing to the group's work.

A number of activities have been initiated in the three months the group has been in existence:

- ◆ a review of WHO published recommendations on injection safety has been carried out, in order to assess discrepancies and facilitate standardisation. Currently work is focusing on recommended sterilisation procedures and equipment;
- ◆ published literature on the adverse effects of unsafe injections has been reviewed in order to document the extent of the problem;
- ◆ a preliminary draft of a medium-term strategy to fight against unsafe injections has been prepared;
- ◆ the outline of a booklet on how to ensure injection safety has been drawn up for district and medical officers. □

For further information contact: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

Approaches to promoting drug availability in South-East Asia

ENSURING access to essential drugs is becoming increasingly difficult. Among the challenges are changing therapeutic needs, the roles of the public and private sectors, globalisation, quality assurance and regulation in pharmaceutical markets, and health reform. These were among the issues debated by delegates at an intercountry consultative meeting on promoting availability of essential drugs in primary health care, held at WHO Regional Office, New Delhi, from 21–25 April 1997. The meeting, which provided an opportunity to exchange country experiences, focused on drug financing and drug supply strategies, with discussions on the advantages and disadvantages of various models. To build on progress already made in the Region, participants prepared national and regional guidelines to improve drug affordability. □

A report of the meeting is available from SEARO, New Delhi (see address above). Document Ref. SEA/Drugs/120.

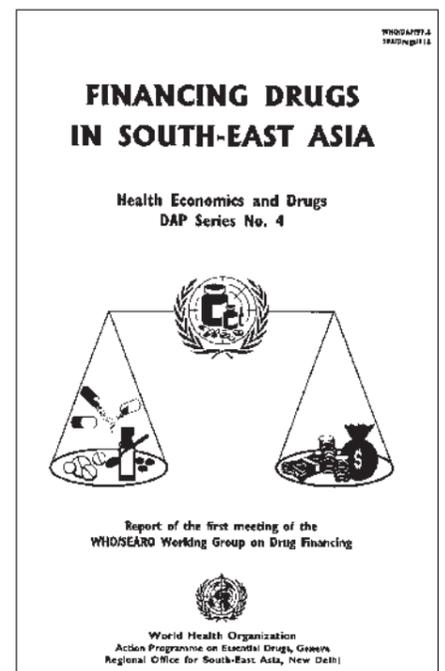
South-East Asia Working Group on Drug Financing

IN response to growing concern about financing of essential drugs WHO's South-East Asia Regional Office has formed a working group on drug financing, with support from DAP. The first meeting of the group was in November 1996, in Thailand, with each of the four participating countries, Indonesia, Myanmar, Nepal and Thailand, sending one essential drugs official and one representative concerned with health reform.

Through presentations, discussions and field visits the group looked at the full range of drug financing options. Participants recognised the need to build on health financing experiences in the

Region, and to develop skills and guidelines in public financing, health insurance, user fees and other finance areas. The group agreed to share information on indicators for drug financing. It will meet next in late 1997 in Indonesia. □

Copies of the meeting report, *Financing Drugs in South-East Asia*, WHO/DAP/97.8 are available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland and from World Health Organization, Regional Office for South-East Asia, World Health House, Indraprastha Estate, Mahatma Gandhi Road, New Delhi 110002, India. Ref. SEA 118.



Productive first meeting for HAI-Central America

OPPORTUNITIES for promoting rational use were thoroughly explored at the inaugural meeting of the Central American HAI (Acción Internacional por la Salud) Network. Held in Matagalpa, Nicaragua, from 23–25 October 1996, participants came from Costa Rica, El Salvador, Guatemala, Honduras, Mexico and Nicaragua. Analysis of the current

pharmaceutical situation in each Central American country clearly identified the scope for improvement but also showed that in some countries constraints were more severe than in others.

Participants identified a number of critical areas for possible HAI intervention in the sub-region: drug registration, problems of drug availability, generic drugs, drug prices, drug promotion,

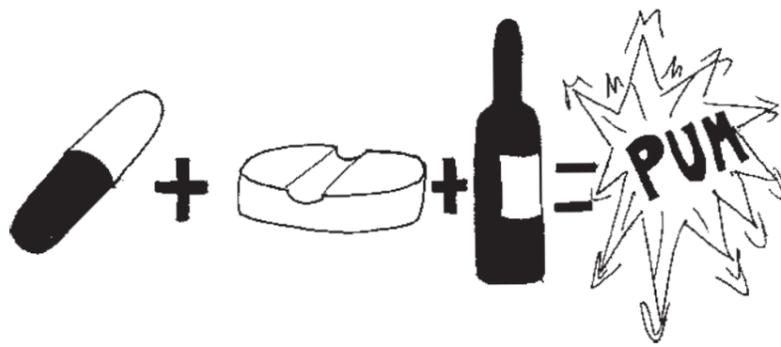
product quality, training of health personnel, options for community-based drug supply, rational use of medicines, consumer information and national drug policy. The group also defined strategies to strengthen the work in each country, exchange experiences, share information and undertake joint activities.

Nicaraguan campaign continues

Building on previous campaigns, the Nicaraguan consumer group, Acción Internacional por la Salud (AIS), has produced leaflets and posters on a number of themes to promote rational drug use. The posters, entitled "Essential Drugs" and "No to Antidiarrhoeals", are accompanied by two complementary packs on drug pricing and use of generics, and the treatment of diarrhoea. The group has already disseminated its rational use message through information packs on cough medicines and antibiotics, and posters on prescribing low-cost medicines, and brand name drugs versus generics. □

Copies of the materials are available, in Spanish only, from: AIS Nicaragua, Apdo. 184, Matagalpa, Nicaragua. Fax: + 505 61 22458.

Reacciones feas al chocar unos medicamentos con otros o con bebidas y alimentos



An AIS poster warns of the possible dangers of mixing drugs and of taking certain drugs with alcohol or food

France: survey shows value of generics

THE French Government could save up to Fr.fr.317 million (US\$63 million) if seven of the most frequently prescribed pharmaceuticals were substituted by generics, according to the consumer magazine, *Que Choisir*, November 1996.

The magazine has published a survey on generic medicines, in which it gives examples of the price differences between generic/copy versions of prescription drugs, and the savings that could be achieved if the least expensive product was prescribed.

For example, prescribing Verapamil-MSD instead of the brand name product would save Fr.fr.54.5 million per year, and savings of Fr.fr.38 million and Fr.fr.31.3 million respectively could be made on Carbocisteine-GNR and Spironolactone-GNR, according to *Que Choisir*.

Noting that the generics market has been slow to take off in France compared to other European countries, the magazine states that much needs to be done to encourage it. □

Source: Scrip No.2183, November 1996.

NEWSDESK

The world health situation

THE *World Health Report 1997: Conquering Suffering, Enriching Humanity* focuses on major chronic noncommunicable diseases, such as cancer and heart disease, diabetes and rheumatic conditions, and mental and neurological disorders. It shows that the bonuses of an increasing life span are in danger of being outweighed by the burden of chronic diseases. Meanwhile the threat of infectious diseases continues, so that the battle for health must be fought simultaneously on both fronts. *The Report* examines and explains the causes of these diseases, and highlights the main risk factors in their development – from genetic influences, to the role of unhealthy life styles that are becoming commonplace.

Ensuring access to and availability of essential drugs and vaccines at low cost, their rational use, and their quality and safety remain a major goal for WHO. *The Report* calls for global application of the essential drugs concept (see box).

The World Health Report 1997 is indispensable reading for all those with a political, professional or personal interest in health. □

Essential drugs for chronic diseases

"Many chronic diseases can be treated effectively with drugs, and every year more of these drugs enter the market, especially in industrialised countries. Some of the new drugs, but not all, represent real therapeutic advances; most are very expensive. They are often taken for long periods, if not for life, which leads to high treatment costs and increased chances of unwanted side-effects. Chronic diseases are increasingly prevalent in developing countries and the need for drugs to treat them is therefore also rising, although they often remain untreated, either because people have no access to regular medical care or cannot afford it.

The best way to ensure the availability of and equitable access to essential drugs, including those for chronic diseases, is to develop standard treatment protocols and lists of essential drugs for different levels of health care, and to use these as the basis for the supply of drugs, for the training and supervision of health workers, and for reimbursement schemes. Essential drugs should be selected on the basis of evidence and in accordance with the criteria used for compiling the Who Model List of Essential Drugs, which is updated every two years.

The need for drug selection is not restricted to developing countries. Health care costs in general and drug costs in particular, are rising everywhere. Most of the increased drug cost is due to the use of new medicines, and many of these are for chronic diseases. In order to ensure an optimal use of limited resources, a careful evaluation is needed of their cost-effectiveness in relation to existing treatment alternatives. Some

industrialised countries have developed very detailed procedures for this difficult process. One example is the pharmaceutical benefit scheme in Australia, which requires proof that a drug is more cost-effective than existing treatments, before it is approved for reimbursement. It is interesting to note that the list used in the Australian scheme contains approximately the same number of active ingredients as the National List of Essential Drugs in Zimbabwe.

Another example is the Scottish intercollegiate guidelines network, which is developing national treatment protocols entirely on the basis of evidence. For every treatment recommendation, the strength of the supporting scientific evidence is indicated according to four levels – the strength of the evidence defines the strength of the recommendation. The main objective of the Scottish guidelines is to attain the highest standards in health care, rather than cost containment. Some of the recommendations lead to increased health care cost, for example in the treatment of diseases which are generally known to be underdiagnosed and undertreated (e.g. diabetic retinopathy).

These two examples show that essential drugs are not for poor countries only or for rural areas only. The concept of essential drugs is just as valid in developed countries, in teaching hospitals, and in health insurance schemes. It is as valid for the treatment of cancer, cardiovascular diseases and metabolic disorders as it is for malaria, acute diarrhoea and pneumonia."

Source: *The World Health Report 1997*.

Copies of *The World Health Report 1997* are available, in English and French, from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.15/US\$13.50, and in developing countries Sw.fr.9.

Updated NDP for Papua New Guinea

PAPUA New Guinea has more than four decades of experience in developing, implementing and financing a unique pharmaceutical supply system. Recently, however, the situation has deteriorated, resulting in shortages of drugs in health facilities. The Department of Health (DOH) is committed to addressing the problems, with the support of various donors. An updated national drug policy was seen by the Government as an important tool to identify the main solutions and to better coordinate the various partners.

A new draft policy was prepared in May 1997 by the DOH and the WHO Regional Office for the Western Pacific, with support from the Action Programme on Essential Drugs. Policy preparation involved:

- consultation with a broad range of people in both public and private sectors;
- the draft of a first outline by a small working group within the DOH;
- a national workshop for discussion of the draft;
- inclusion of all comments received.

The document was circulated further and accepted at the National Health Conference in June 1997, prior to

endorsement by the National Executive Council and implementation through a structured plan.

The main approaches in developing and implementing the plan will be: partnership between the major players; increased coordination within the health sector; inter-sectorial cooperation with

departments, such as Customs, Finance, Education and with Provincial Authorities; increased responsibilities for local authorities; and technical cooperation with other countries and international agencies in such fields as drug evaluation, drug information exchange, quality control, technology transfer and training. □



Photo: WHO/J. Abcede

The importance of health education is recognised in Papua New Guinea's new drug policy. Here pregnant and nursing mothers learn more about nutrition

Guiding NGOs on essential drugs policies

WHILE many nongovernmental organizations (NGOs) advocate the adoption of essential drugs policies by national governments, few have actually implemented the same policies to guide their own activities. This has prompted *A Guide to NGO Essential Drugs Policies*, which explains why following an essential drugs policy is important, and then sets out a step-by-step approach to help NGOs develop such a policy.

The issues addressed in the *Guide* include assessing needs, selecting drugs, financing a sustainable drug supply and controlling drug donations. These issues were chosen based upon the results of a survey conducted among European development aid NGOs.

The *Guide* includes a list of useful addresses and a summary of key resources. □

Copies of *A Guide to NGO Essential Drugs Policies* are available, free of charge, from: HAI-Europe, Jacob van Lennepkade 334-T, 1053 NJ, the Netherlands. Tel: + 31 20 683 3684, fax: + 31 20 2111685 5002, e-mail: hai@hai.antenna.nl

NETSCAN

Update on South Africa

Key documents relating to South Africa's drugs policy and Essential Drugs Programme have been put on the Internet. This has been done by HealthLink, a project established to help meet the communication and information needs of health workers, in collaboration with the South African Drug Action Programme and the Department of Health. The address is: <http://www.healthlink.org.za> under "Info. Resources"

Or if your browser does not support frames:

<http://www.healthlink.org.za/hst/edinfo.htm> (Essential Drugs List)

<http://www.healthlink.org.za/hst/ndp/a.htm> (National Drug Policy)

The South African Primary Health Care

Formulary, which includes the standard treatment guidelines and essential drugs list, is also available at the HealthLink address.

**Drug bulletins on line**

The Swiss drug bulletin *Pharma Kritik* can be found at: <http://www.informed.org> and contains full texts of articles since 1995, an evaluation of the 100 most important drugs and links to other medical sites. A test shows which of the many Medline sites are the best and which are still free of charge.

The Australian Prescriber's homepage includes the full text of articles from 1995 and links to other sites. It can be found at: <http://www.medfac.unimelb.edu.au/ap>

In March 1997 the UK's *Drug and*

Therapeutics Bulletin launched a CD ROM containing all the articles published between 1993 and March 1997. Subscribers will receive a new disk that includes the latest issues every six months. Contact: Drug and Therapeutics Bulletin, 2 Marylebone Road, London NW1 4DF, UK. Fax: + 44 171 830 7541, e-mail: pictonc@which.co.uk

And also...

The European Evaluation Agency provides the European Public Assessment Reports on the Internet. The Agency's web site address is: <http://www.eudra.org/emea.html>

Public Citizen Health Research Group's web site can be found at <http://www.citizen.org/hrg>

**DAP's homepage**

The Action Programme on Essential Drugs' homepage on World-Wide-Web introduces users to the essential drugs concept, national drug policies, and the work of WHO and the Action Programme. The information, which is frequently updated, is being made even more user friendly.

The titles of selected WHO, DAP and other pharmaceutical publications are available on the homepage. A new feature is the availability of the complete English, French and Spanish versions of the *Monitor* (from number 22 onwards) in PDF format. In addition, text from other selected DAP publications can be viewed and downloaded. For example, users can print out the *Guidelines for Drug Donations* and *Guide to Good Prescribing*.

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



MEETINGS & COURSES

Dates for clinical pharmacists

Future therapies and clinical pharmacy will be the theme of the 26th Annual Symposium of the European Society of Clinical Pharmacy (ESCP), which will be held in Tours, France, from 15–17 October 1997. Co-sponsored by the French Society of Clinical Pharmacy, the symposium offers a varied programme of lectures, workshops and poster sessions.

Next year, for the first time, ESCP will devote a conference entirely to pregnancy and child health, covering current concepts in the therapeutics, pharmacokinetics and clinical evaluation of medicines in these fields. The conference will be held in Budapest, Hungary, from 22–25 April 1998.

For further information on the Annual Symposium contact: Secretariat E.S.C.P. – Tours 1997, Centre International de Congrès VINCI, 26 Boulevard Heurteloup, B.P. 4225, 37042 Tours Cedex 1, France. For more details of the Conference on Mother and Child Health contact: Secretariat ESCP, Budapest 1998, Coopcongress Hungary, Convention Centre Budapest, Jagello u. 1–3, H-1121 Budapest, Hungary.

**Procurement models on agenda in Pacific**

As part of the increasing focus on drug issues in the Pacific Island States a workshop will be held in Nadi, Fiji, from 11–13 November 1997. The workshop will provide an ideal opportunity to promote exchange of technical information on all pharmaceutical matters, as staff responsible for procurement, drug registration and quality assurance will come from 20 countries/areas in the Region. Specific objectives are to discuss: various models for drug procurement, (including possible bulk purchase for selected drug products, tender requirements and procedures, and quality assurance of drug supply systems); the use of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce; and the interagency *Guidelines for Drug Donations*.

Improve your drug supply management skills

The International Dispensary Association (IDA), of the Netherlands, and Management Sciences for Health, of the USA, are again joining forces in Amsterdam to run a second 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 6–17 October 1997. 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\$3,500 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

**South Africa: pharmacotherapy teaching course**

The second African course in Pharmacotherapy Teaching will be held at the University of Cape Town from 24 November – 3 December 1997. The course will be run by the University in collaboration with the Action Programme on Essential Drugs. The aim is to teach teachers of pharmacology and therapeutics to equip

their students with adequate skills and knowledge to prescribe drugs rationally. The course will enable participants to plan, develop and implement this problem-based teaching method at their local medical school or teaching institution. The course is based on the methodology developed by the University of Groningen in the Netherlands (see EDM-20). The course fee is US\$ 3,000 which includes board and lodging, tuition fees, and educational materials but excludes travel expenses.

For further information contact: S. Koonin, Department of Pharmacology, Medical School, University of Cape Town, Observatory 7925, South Africa. Tel: +27 21 406 6355, fax: + 27 21 448 0886.

**Nepal hosts rational use course**

The next INRUD/DAP course on Promoting Rational Drug Use will be held in Kathmandu, Nepal, from 15–26 March 1998. Topics will include identifying drug use problems, developing and evaluating interventions, and the development of public and prescriber educational materials and campaigns. Course work will be highly participatory and very practically oriented.

For further information contact: Management Sciences for Health, 165 N. Fort Myer Drive, Suite 920, Arlington, VA 22209, USA. Tel: +703 524 6575, fax: +703 524 898, e-mail: inrud@msh-dc.org

**H.E.L.P. 97**

Health Emergencies in Large Populations, a training course on the management of humanitarian assistance, will be held in Addis Ababa from 3–21 November 1997. Organized jointly by the International Committee of the Red Cross and WHO, the H.E.L.P. course is intended particularly for doctors, nurses, nutritionists, environmental health engineers and epidemiologists. Candidates from

countries affected by war and natural disasters will be given special consideration. The course covers eight interrelated fields: planning, health services, coordination, food and nutrition, environmental health, communicable diseases, epidemiology and international humanitarian law.

Registration fees are US\$500, and minimal living expenses for the three weeks should be between US\$650 and US\$900.

For further information contact: International Committee of the Red Cross, Health Division, H.E.L.P. 97, 19 avenue de la Paix, 1202 Geneva, Switzerland. Tel: +41 22 730 2725, fax: 1 41 22 733 9674, e-mail: opsan_gva@icrc.org

**Anthropology of health care: course in Bangladesh**

Anthropological research can provide insights into people's perspectives of health and health care, and can therefore help primary care programmes meet the population's needs more effectively. An International Course on the Anthropology of Health and Health Care will be held in Dhaka, Bangladesh, from 7 February to 19 March 1998 for junior social scientists and public health professionals interested in sociocultural aspects of care. The course, designed to provide a working knowledge of anthropological concepts and methodological research tools, will focus on various problem areas, such as implementation of primary health care, self-care and reproductive health. The faculty is made up of a team of experienced researchers from Asian institutions and from the Netherlands.

Course fees are US\$3,950, plus accommodation (US\$15 per day) and food (US\$10–15 per day). The closing date for applications is 15 December 1997.

Application forms are available from: The Director Research, Bangladesh Rural Advancement Committee, 75 Mohakhali C.A., Dhaka-1212, Bangladesh. Tel: + 880 2 883542, fax: + 880 2 883542, e-mail: red@amrbrac.bdmail.net



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.

Health Economics: Drugs and Health Sector Reform, WHO Task Force on Health Economics, WHO/TFHE/96.2, 1996, 18 p.

Is the present socio-economic model of development adopted in many countries compatible with basic public health principles? Are the market economy, privatisation and free enterprise the solutions for all health sector problems? And in an environment where the state is supposed to play the smallest possible role, who can guarantee equal access to health services? This paper addresses these fundamental questions and aims to stimulate debate on new ways of structuring health services. It argues that the prevalent concept of society is focused on economic growth with little concern for equity. The role of WHO is to explore new models and suggest ways to organize health services that respond better to the objectives of efficiency and equity.

As well as discussing the challenges of globalisation, the publication analyses health sector reform, including problems, principles, objectives and proposals for financing, organization and administration. The final section examines the importance of the essential drugs concept in health reform. The publication concludes that changes cannot succeed if the organizational structure of the pharmaceutical sector and relations between state, public and private providers, and the population remain unchanged.

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

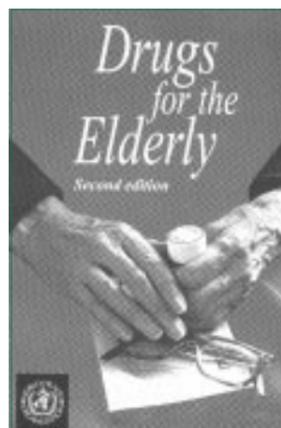
Comparative Analysis of National Drug Policies, Second Workshop, Geneva, 10-13 June 1996, WHO, WHO/DAP/97.6, 1997, 114 p.

There have been very few studies to compare national drug policies and to discover which have been successful – and why – in achieving the goals of availability, accessibility, good quality and rational use of drugs. This document describes the preliminary findings of such a study, as discussed in a workshop organized by the Action Programme in June 1996. The study was initiated by DAP in collaboration with the Division of International Health Care Research (IHCAR), Stockholm, and the Harvard School of Public Health in Boston, USA (see EDM-19). Research was carried out by national teams in 12 countries (Bulgaria, Chad, Colombia, Guinea,

Drugs for the Elderly, 2nd ed., WHO, Regional Office for Europe, 1997, 155 p.

During the last decade the ageing of the world's population has stimulated interest in the use and misuse of drugs in the elderly. The second edition of WHO's publication is a quick reference guide to the differences between the old and the young with regard to drug therapy. It also points to alternatives to drug therapy whenever these are safe and effective. Main sources of information and suggestions for further reading are included in an annex.

Available from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.32/US\$28.80, and in developing countries Sw.fr.22.40.



WHO Expert Committee on Specifications for Pharmaceutical Preparations: Thirty-fourth Report. WHO, Technical Report Series No.863, 1996, 194 p.

The report sets out 12 international guidelines and other recommendations intended to assist national drug regulatory authorities and manufacturers in the quality control of pharmaceutical products. The most extensive guidelines concern global standards and requirements for the regulatory assessment, marketing authorisation and quality control of multisource drugs. The report also contains revised guidelines for implementation of the WHO Certification Scheme on the Quality of Pharmaceutical Products Moving in International Commerce. These include standardised format and contents for product and batch certificates issued by the drug regulatory authority of the exporting country and the manufacturer. The section on stability testing focuses on how to

predict the stability of a drug product and determine its shelf-life and storage conditions in various climatic zones. Previously issued advice on good manufacturing practices is supplemented, to cover validation of the manufacturing processes, and the manufacture of investigational products for clinical trials in humans and herbal medicinal products.

The report is of particular importance in countries attempting to establish or strengthen a regulatory framework for pharmaceuticals.

Available, in English and French, (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.

International Conference on National Medicinal Drug Policies – The Way Forward, Australian Prescriber, Volume 20, Supplement 1, 1997, 272 p.

In October 1995, 300 people from over 40 countries met in Sydney to explore ways in which enlightened, broad-based, actively implemented national medicinal drug policies can meet both health and economic needs, (see EDM-21). The Conference, sponsored by the Australian Government and the Action Programme on Essential Drugs, focused on equity of access to medicines, rational use, quality and the contribution of the pharmaceutical industry to public health goals. This supplement from the *Australian Prescriber* contains overviews of each part of the conference, and edited versions of the presentations made by representatives from governments, NGOs, the health professions, academia, consumer organizations and industry.

Available from: Pharmaceutical Education Programme, Pharmaceutical Benefits Branch, Department of Health and Family Services, P.O. Box 9848, Canberra ACT 2601, Australia. Tel: + 61 6 289 7491, fax: + 61 6 289 8846.

Australian Drug Information Procedure Manual, The Society of Hospital Pharmacists of Australia, 1996, 65 p.

A comprehensive guide to the establishment and maintenance of drug information centres, the *Manual* sets out uniform standards of practice in the evolving field of drug information. It provides guidelines on enquiry taking, processing, recording and quality assurance procedures for drug information. Sections also cover available resources for information retrieval, literature evaluation, clinical trial design and ethical and legal issues.

The *Manual* will help both hospital and community pharmacists meet the demand for objective, evidence-based data to be readily available when decisions on patient care are being made.

Available from: The Society of Hospital Pharmacists of Australia, Level 11, 114 Albert Road, South Melbourne VIC 3205, Australia. Price: AU\$49.00 plus postage.

Power, Patents and Pills, Health Action International, 1997, 30 p.

In October 1996, HAI-Europe and BUKO Pharma-Kampagne organized a seminar on GATT/World Trade Organization, Pharmaceutical Policies and Essential Drugs (see EDM-22). *Power, Patents and Pills* provides a summary of the papers presented and discussions which took place during the seminar. Speakers were selected to represent the various key actors involved in international pharmaceutical policy: the medical community, WHO, WTO, consumer organizations and health researchers and activists.

Available from: Health Action International, Jacob van Lennepkade 334-T, 1053 NJ Amsterdam, the Netherlands. Price: D.fl 15, but reduced rates for groups in developing countries. E-mail: hai@hai.antenna.nl

Drugs of Choice: A Formulary for General Practice, 2nd. ed., M. Levine, J. Lexchin, R. Pellizari, 1997, 278 p.

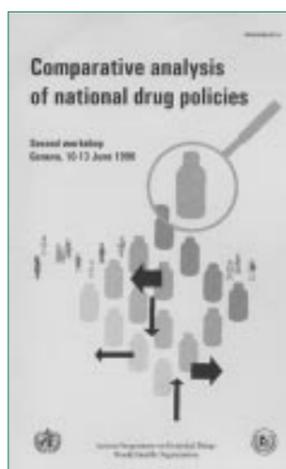
This is an evidence-based book of prescribing information organized around diagnoses/problems for which general practitioners in Canada would initiate therapy. The expanded edition includes recommendations for 177 different conditions. Besides being available as a wire-bound book there is also a disk version (for Windows only).

Available from: Canadian Medical Association, Membership Services, P.O. Box 8650, Ottawa, ON, Canada K1G 0G8. Fax: + 613-731-9013. Price: Book or disk CAN\$19.95, book and disk CAN\$24.95, plus shipping and handling costs.

Health Economics: A Guide to Selected Literature, Supplement: Jan. 1994 – May 1996, WHO, WHO/TFHE/96.3, 1996, 81 p.

Since the appearance of the first Guide to selected WHO literature on health economics in 1994, the increasing number of publications, articles and documents on the subject within the Organization has made it useful to compile a supplement. Material produced by WHO programmes or published by staff members has been selected with the aim of providing up-to-date information on subjects related specifically to health economics, and of ensuring a balance in both geographical scope and coverage of WHO programme areas. The summaries have been indexed for ease of reference, and are classified under the following headings: international economics and health; macroeconomics and health; health care financing; economic evaluation; work within WHO programmes; and country case studies.

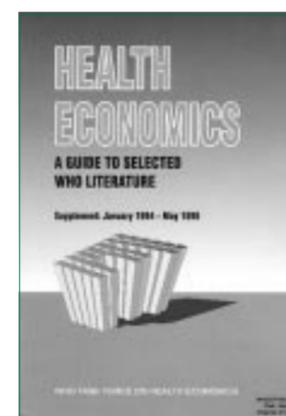
Available, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.



India, Mali, Philippines, Sri Lanka, Thailand, Viet Nam, Zambia and Zimbabwe).

The workshop focused on: providing methodological support to the research teams; reviewing research results; assessing the two main research tools used (standardised NDP indicators, to assess NDP performance, and political mapping for analysis of NDP formulation and implementation processes); and preparing a plan for the finalisation and dissemination of the research findings.

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



Le secteur pharmaceutique privé commercial au Sénégal, (The private pharmaceutical sector in Senegal), WHO, DAP Research Series No.23, WHO/DAP/97.3, 1997, 36 p.

Between 1993 and 1994 a research team of doctors, pharmacists and economists assessed the private pharmaceutical sector's contribution to the accessibility and rational use of essential drugs in Senegal. The study reported here was carried out in several stages, and involved interviews with wholesalers and at pharmacies and drug warehouses. It found that the private sector makes up more than 80% of the official drug market, with more than 75% of the country's pharmacists working in this sector.

Research revealed great disparity in drug availability between the area around the capital, Dakar, where dispensaries are largely concentrated, and other regions. In general, however, the study showed a high level of

availability of essential drugs in dispensaries and a well functioning distribution network. For example, a survey conducted at 20 dispensaries to assess the level of availability of 18 essential drugs found them present in 98% of cases. Self medication and use of the parallel drug market are frequent. The report also discusses the profound effect that devaluation of the CFA franc, in January 1994, has had on drug prices in Senegal. For example, by April that year prices had increased 49% and sales had dropped 29% compared with 1993.



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

La libéralisation du secteur pharmaceutique en Algérie, (The liberalisation of the pharmaceutical sector in Algeria), WHO, DAP Research Series No. 22, WHO/DAP/97.2, 1997, 37 p.

This document focuses on the impact that liberalisation of the pharmaceutical sector has had on the price and availability of essential drugs in Algeria, and on the organization of the sector – particularly on imports, and wholesale and retail distribution. It reports on a three-year study at a sample of dispensaries throughout Algeria, analysis of available data, and discussions with the main actors in the pharmaceutical sector.

The study concludes that the private pharmaceutical sector has expanded rapidly, but that regulatory activities have not kept pace with the rate of change. The study reveals significant price increases, drug shortages and

problems of availability, which vary depending on the region and the supplier. The reduction in purchasing power of the majority of the population, the social security system's diminishing resources, the relative decrease in the proportion of the national budget given for pharmaceuticals, and the growth of the private sector have clearly reduced financial access to pharmaceutical products in Algeria, the report states.

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

International Nonproprietary Names (INN) for Pharmaceutical Substances: Cumulative List No.9, WHO, 1996, 885 p.

This publication groups together the 6567 international nonproprietary names published by WHO up to December 1995. The list features INNs presented in alphabetical order under the Latin name and each entry includes equivalent names in English, French, Russian and Spanish. Also given is the molecular formula and the corresponding Chemical Abstracts Service (CAS) registry number.

Separate indexes allow retrieval of the INN equivalent in relation to the national name; the name of the substance from knowledge of its formula; or the name

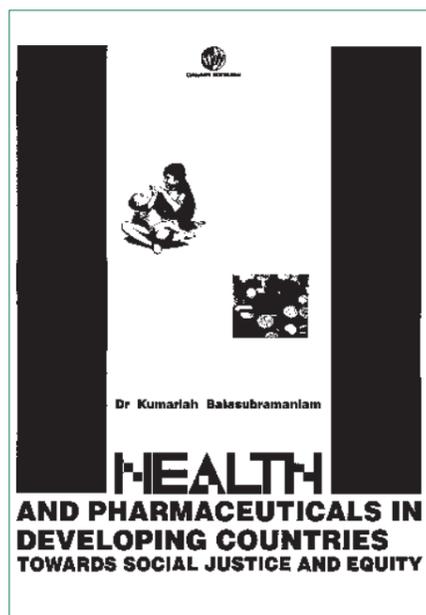
according to its CAS registry number. INNs for substances which are no longer marketed or which were abandoned before marketing are listed in an annex. Procedures for the selection of recommended INNs, and the general principles for guidance in devising INNs are also explained at length.

Available (bilingual English/French) from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.250/US\$225, and in developing countries Sw.fr.175.

Health and Pharmaceuticals in Developing Countries. Towards Social Justice and Equity, K. Balasubramaniam, 1996, 215 p.

The optimistic message that health for all need not be a utopian dream is central to this collection of papers, which has been divided into three broad categories: health, pharmaceuticals, and undergraduate medical education. The author examines the options or alternatives suggested by expert groups or implemented by individual countries in these areas. He advocates the implementation of national health and drug policies based on the concepts of primary health care. The papers will be useful to everyone interested in the problems of ensuring regular access to health care and universal access to a limited number of essential drugs.

Available from: Consumers International, Regional Office for Asia and the Pacific, PO Box 1045, 10830 Penang, Malaysia. Price: US\$10 for developed countries, US\$5 in developing countries.



Practical Guidelines for Preventing Infections Transmitted by Blood or Air in Health-Care Settings, AHRTAG, 1996, 25 p.

People who nurse, treat and comfort patients, friends or relatives who have infectious diseases have always faced some personal risk. Usually the risk is extremely small and is readily overcome by simple precautions. This briefing paper from the Appropriate Health Resources and Technologies Action Group (AHRTAG) discusses the role of blood- or air-borne infections to both carers and patients. The focus is on how to prevent transmission of hepatitis, HIV and tuberculosis, for those working in

resource-constrained situations. Learning more about strategies for avoiding these infections will help prevent the transmission of other infections. The paper also highlights issues for those concerned with policy formulation and with the occupational health training needs of health workers.

Available from: AHRTAG, Farringdon Point, 29–35 Farringdon Road, London EC1M 3JB, UK. Price: £5/US\$10, and free to developing countries.

Le secteur pharmaceutique privé commercial au Maroc, (The private pharmaceutical sector in Morocco), WHO, DAP Research Series No.21, WHO/DAP/97.1, 1997, 44 p.

This is a report of a study which evaluated the extent of the private pharmaceutical sector's contribution to the availability, accessibility and rational use of drugs in Morocco. The research project involved analysis of statistical information and publications, and a study undertaken at 19 dispensaries and a warehouse between April and May 1994. It shows that the Moroccan market is characterised by the wide availability of brand name products under different forms and dosages. The private pharmaceutical sector dominates production, importation and distribution. Drug prices are high in relation to income levels and drug availability is largely concentrated in urban areas where earnings are greatest.

The researchers conclude that three main factors affect access to drugs: geographical location, income level and the level of health insurance. Only 13% of the population are covered by health insurance, and the document discusses the need for a compulsory insurance system and a medical assistance fund for the poor. It also examines the implications for the pharmaceutical sector of Morocco's signing the GATT Agreement and a cooperation agreement with the European Union in 1995.

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

Good Pharmacy Practice (GPP) in Community and Hospital Pharmacy Settings, WHO, WHO/DAP/PHARM/96.1, 1996, 10 p.

The booklet is addressed to national pharmaceutical organizations to encourage them to focus the attention of community and hospital pharmacists on developing the service they provide. It sets out the framework for good pharmacy practices and covers the pharmacist's role in health promotion, supply and use of prescribed medicines, self-care, and influencing prescribing and rational use of medicines.

The booklet emphasises that as national conditions and needs differ greatly, local pharmacists must play an active role in deciding what standards are achievable.

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

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

The Action Programme on Essential Drugs produces a global index of 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:

- ◆ Australia's *Injectable Drugs Handbook*, 1997. The Society of Hospital Pharmacists of Australia. A comprehensive reference of more than 300 injectable drugs, which offers concise referenced information commonly sought by nurses and pharmacists at ward level. Monographs are organized in alphabetical order by generic name.
- ◆ Belgium's *Repertoire Commenté des Médicaments*, 1997. Centre Belge d'Information Pharmacothérapeutique, intended to promote rational prescribing by doctors, pharmacists and dentists. Drugs in 14 therapeutic groups.
- ◆ Nepal's *Manual of Drugs and Therapeutics*, 1996. Tribhuvan University. The first part deals with the principles

of rational prescribing. This is followed by a comprehensive section on therapeutics and the practical aspects of diagnosis and treatment of about 500 diseases/disorders. The manual concludes with a formulary containing prescribing details for essential drugs.

- ◆ Papua New Guinea's *Medical Store Catalogue*, 1996. Department of Health. Contains the essential drugs list and lists for supplies and equipment.
- ◆ Zimbabwe's *Management of Sexually Transmitted Diseases*, 1997. The Zimbabwe Essential Drugs Action Programme. Directed particularly to primary health care workers, all the sexually transmitted disease syndromes encountered in Zimbabwe are covered.

Drug bulletins and newsletters

- ◆ Zimbabwe's Drug and Toxicology Information Service and the Drugs Control Council have teamed up to produce the new *Drug Information Bulletin*, which replaces the DATIS Bulletin. The newsletter's aim is to

bring unbiased information on health issues and medicines to the country's health workers. The first issue features articles on malaria and mushroom poisoning, together with news from the Drugs Control Council.

TRAINING

Drug advertisements: a critical lesson for Indonesian students

➤ SRI SURYAWATI,
BUDIONO SANTOSO*

INFORMATION on drugs and therapeutics is undoubtedly of paramount importance in keeping doctors updated about the most recent medical advances and in maintaining their standard of practice. Unfortunately in many parts of the world objective and unbiased information is a luxury which is difficult for most practitioners to access. In contrast, pharmaceutical information from commercial sources is far more readily available, although often biased and with a tendency to promote the use of specific brand name drugs¹. Yet during their formal training doctors are rarely equipped with the requisite knowledge and skills to critically assess drug information and advertisements. Faced with the huge volume of materials produced by pharmaceutical companies, this weakness in their education may contribute to irrational prescribing by doctors².

To rectify this situation the University of Gadjah Mada, Indonesia, has designed and introduced a teaching module to improve medical students' ability to assess information and advertisements critically. This report of a field test on the module's effect shows that such training sessions achieve their goal of sensitising medical students' assessment skills, and that they have a long-term impact. As a result the module has been incorporated as an assessed element into the clinical pharmacology course in the University's Medical School.

A PROBLEM-ORIENTED APPROACH

Teaching consists of two sessions, the first lasting an hour and the second, two hours. The first session involves a brief lecture about: commercial and non commercial sources of drug and therapeutic information and the characteristics of each source, type and form of such information; how to search and choose the appropriate information in a certain situation; how to select and use the information; and the main elements required to critically assess commercial drug information. WHO's Ethical Criteria for Medicinal Drug Promotion³ are then introduced and intensively discussed. The Criteria contain a list suggesting the type of information which advertisements to health professionals should include. The list is based on a sample drug information sheet found in the second report of the WHO Expert Committee on the Use of Essential Drugs⁴. The list in the Criteria is adapted and condensed into four components – appropriateness of:

- ◆ indication(s)/clinical efficacy;
- ◆ pharmacological (kinetic and dynamic) information;
- ◆ information on dosages and administration;
- ◆ and information on clinical safety, including side effects with common and rare evidence, warnings, precautions and contraindications.

Apart from the four components of information, students are also exposed to examples of misleading messages in drug advertisements from Indonesia and from other countries, to illustrate the extent of

the problem. These messages include exaggerated claims or the extension of indications without substantial scientific support; misinformation on adverse effects to minimise potential hazards; inappropriate recommendations for drug use and dosage schedules; incorrect



A pleasant setting for group discussion, which is seen as an important part of the training module

information on pharmacokinetic and pharmacodynamic profiles; and insufficient warning and precautions information.

In the second session students are asked to critically assess selected drug advertisements from local medical journals, using the four components of information, and decide if misleading information is included. Students work on their own and are given worksheets and standard scientific textbooks or handbooks on drugs and therapeutics as references. Group discussions on their findings follow.

SUCCESSFUL EVALUATION

Twenty-three medical students who were about to start their clinical internships took part in the field test. Recruited from volunteers, their selection was based on two criteria: that the student should have some knowledge about clinical problems; and ideally should not have been influenced by the prescribing behaviour of their clinical tutors. After 12 months, another 13 volunteers at the same stage in their medical training were used as an additional control group.

The field test used a pre- and post-test randomised controlled group design. Students were randomly assigned into two groups: Group A (n=11) underwent training, and Group B (n=12) served as

controls. Two weeks before and two weeks after the training sessions, Group A and Group B underwent pre- and post-testing respectively, with a final test 12 months after the intervention. Another group of students, Group C (n=13), who were never involved in the training, were recruited for this final test. Ten drug advertisements selected from leading Indonesian medical journals were used as test materials. Students had to critically assess the advertisements, to evaluate the appropriateness of information on indications, safety and efficacy, dosage and use, pharmacokinetics, and other relevant information. Their ability to critically assess drug advertisements was assumed to be reflected by the number of examples of misleading or incorrect information identified. The change in the number of examples found before and after the intervention between groups was tested using analysis of variance followed

by t-test. Long-term impact of the intervention was measured by comparing the number of items of misleading/incorrect information identified by the three groups at the final test, 12 months later. A peer group of experts cross-checked the students' objective evaluation of the advertisements.

The students' subjective responses were substantiated by the findings during the pre-test, 2-week, and the 12-month post-tests, when they again had to evaluate published drug advertisements (see table). The students who underwent training (Group A) could correctly identify more examples of misleading information two weeks after the intervention than before it ($15.0 \pm \text{SEM } 1.7$ vs. $5.8 \pm \text{SEM } 0.6$). This difference was statistically significant (t-test, $P < 0.02$). In contrast, the control group (Group B) did not demonstrate any difference in the number of items of misleading or incorrect information that they could identify during the pre-test and the two week post-test ($6.7 \pm \text{SEM } 0.7$ and $5.9 \pm \text{SEM } 0.6$ respectively).

After 12 months Group A still demonstrated their ability to critically assess drug advertisements (15.8 ± 1.2). The score obtained by Group B increased at the final test, probably due to

cross-contamination, while Group C's score was only 7.9 ± 0.9 .

AN EXAMPLE TO BE FOLLOWED

The difference in the number of examples of misleading information identified by the intervention group as compared to control groups suggests that the intervention succeeded in improving knowledge and skills to critically assess drug advertisements. Misleading or incorrect information identified by the students included: paracetamol as a cure for all headaches; multivitamins promoted for the prevention of physical and mental exhaustion and tiredness; vitamins as adjunctive therapy to antibiotic treatment; and assertions that as a drug is new it must be the most powerful.

All the students who received training recognised its importance. They felt that they were better able to understand how to critically assess drug advertisements, and how to search and to use drug information appropriately. They also expressed the view that similar training should be introduced for all medical students.

Our experience indicates that this training module can be implemented effectively in existing medical curricula, after adaptation to local circumstances. In most developing countries the flood of drug advertisements received by physicians cannot be controlled or avoided. It is therefore imperative that practitioners should be properly equipped with the knowledge and skills to evaluate them. □

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Number of examples of misleading/incorrect information in 10 selected drug advertisements identified by the intervention and control groups (mean \pm SEM)

Group	Pre-test	Post-test	12-month test
Group A (intervention, n=11)	5.8 \pm 0.6	15.0 \pm 1.7*	15.8 \pm 1.2*
Group B (control, n=12)	6.7 \pm 0.7	5.9 \pm 0.6	11.4 \pm 1.1
Group C (control, n=13)	–	–	7.9 \pm 0.9

* Significantly different compared to controls. Student's paired t-test, $P < 0.02$

TRAINING

Next! is definitely not enough for Zimbabweans

➤ CHARON LESSING, HEATHER MOORE, AIDAN CHIDARIKIRE*

Next is not enough, is a training package uniquely designed through the combined efforts of health workers and the Zimbabwean public to address issues of concern to both groups. The package is not about diseases or drugs, but about people, attitudes and effective communication. Its title derives from the frequent call of "Next" that punctuates the daily coming and going in health centres.

As a first step, the Information, Education and Communication (IEC) Task Force of the Zimbabwe Essential Drugs Action Programme (ZEDAP) conducted an extensive IEC literature search and situation analysis. Later the group met with some 50 other representatives of the Zimbabwean community to discuss issues related to IEC and rational drug use. This collaborative meeting identified areas of concern and prioritised two main problems:

- poor health worker – patient interactions
- lack of impartial drug-related information

The Task Force, joined by a DAP staff member, then discussed possible strategies for solving the problems identified. Strategies were ranked according to the criteria of cost, chance of success, penetration, available expertise and sustainability (see table). A training package and video to improve patient-health worker interactions, intended for use by both groups, received high scores for feasibility and possible impact, and was therefore adopted.

This strategy was considered realistic because:

- Ministry of Health decision makers and the health workers themselves recognise the need for improved communications;
- there is a high level of awareness of consumer rights and the need for quality service from health workers in Zimbabwe;
- national experience already exists in the use of video/film in public and health worker education;
- there are good facilities and expertise available in Zimbabwe to produce videos;
- Ministry of Information mobile film units are very active and reach even the remotest areas.

Once again consulting with a wider audience, the Task Force designed a story describing a patient's visit to a clinic where the nurse is uncaring and uncommunicative. In order to ensure a realistic approach, the story line was developed after filming at a local clinic for a day, and then asking health workers to comment on activities and attitudes revealed by the film.

The training video depicts a typical nurse – patient interaction. A narrator

then takes the audience through the scene, pointing out areas that could be improved. This is followed by the same encounter but reshot this time with effective interaction between patient and health worker. The main messages are reinforced through the narration and also by key points flashed on the screen.

ONE PART OF THE PACKAGE

The video is only part of the training programme – the package also consists of written notes for a four-hour training session to be integrated into the curricula of all the schools of health (doctors, pharmacists, pharmacy technicians, nurses). There is also a shorter programme for in-service training needs. Unlike most training sessions there are no lectures to



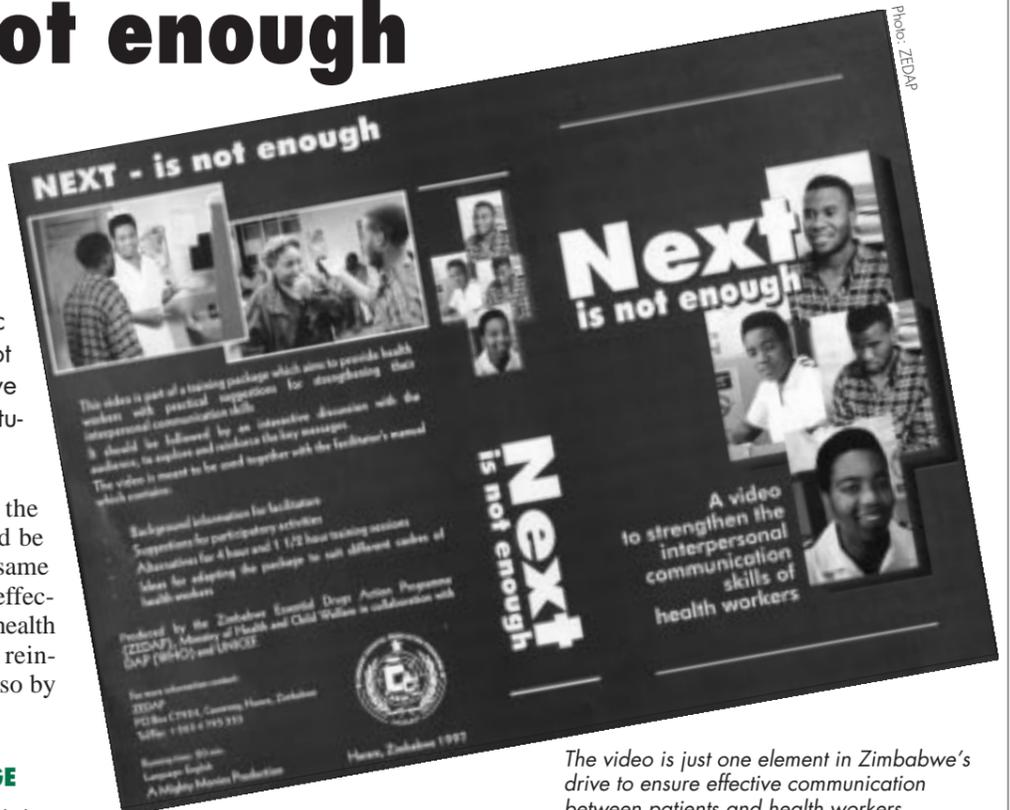
Making the video: cameras roll at a health centre

be given, no notes to be taken, just an intensive behavioural experience to be had. The package takes participants through a series of highly interactive and participatory exercises, building on the messages put across in the video and developing communication skills and positive attitudes.

The enthusiasm surrounding the project is easy to understand considering the level of involvement of the target audience in the production of this package – from nurse students as the main actors to the heads of the different Ministry of Health departments. Equally important was the involvement of "outside" expertise from WHO's Action Programme on Essential Drugs and UNICEF (Zimbabwe) – who offered their resources and endorsement.

FOCUSING ON THE CONSUMER

Just as the video is only part of the training package, the package is only part



The video is just one element in Zimbabwe's drive to ensure effective communication between patients and health workers

of a wider IEC project. Successful therapy ultimately depends on consumer participation in, and understanding and acceptance of the offered therapy. This requires mutual respect and effective communication by both parties.

Using experience gained in the production of the first training package, together with the strong international and national partnerships developed, work will soon begin on a complementary package. In balancing the relationship between the health worker and the consumer, this second package will seek to empower the consumer to actively participate in any interaction with a health service provider. □

Photo: ZEDAP

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The ZEDAP Task Force

The ZEDAP Information, Education and Communication Task Force benefits from broad representation from the Ministry of Health (Pharmacy, Nursing and Health Education), the consumer rights body, the pharmaceutical industry, the University School of Medicine, and NGOs.

3 Key Messages

- Respect your patient
- Communicate effectively
- Establish a warm and caring relationship

Priority ranking of strategies

Criteria*	Cost (inverse)	Chance of success	Potential reach/uptake	Expertise available	Sustainability	Total	Rank
HW training workshops	1	4	5	2	0	12	medium
written material	0	0	1	2	0	3	low
community training video	2	5	4	5	4	20	high
radio	1	2	4	4	1	12	high
student training video	2	5	4	5	4	20	medium
others**							

(* Criteria ranked 1-5)
(** Many other strategies were discussed but are not included here)

