When Bangladesh launched its pioneering national drug policy in 1982, it was the first country to develop a policy based on internationally accepted public health concepts such as primary health care and the need for essential drugs. The objectives were to ensure increased availability and accessibility of good quality essential drugs; to eliminate useless, non-essential and potentially hazardous drugs from the market; to encourage local manufacture; to develop a comprehensive legislative framework, and to promote the use of generic drugs. That progress has been made towards many of these goals can be seen from the ten year policy review reported on page 10.

The Bangladesh policy was drafted by an eight person committee of experts, working rapidly and confidentially. The government feared that if this work were publicly known, outside pressure could inhibit the policy's development, scope and adoption. Its launch encountered fierce opposition - mainly from industry and the medical association - which forecast dire consequences for medical care. They also bitterly criticized their non-involvement in the development process. This opposition, although attenuated over the years, has never fully abated. We cannot know whether the policy would have seen the light of day in anything like its present form had it been the result of a participatory process of all actors in the pharmaceutical sector. It is never easy to break new ground. But it is evident that resistance concerning this non-involvement has played a part in efforts to undermine and overturn core elements of the policy. It is significant that in the review process currently underway all participants in the pharmaceutical sector are fully represented.

If ten years ago Bangladesh broke new ground in the developing world, Australia is today doing the same for developed countries. It is sometimes argued that developed countries have no need of a "pharmaceutical policy" as such; that all the necessary elements are already in place in their comprehensive legislative and educational infrastructure. Yet published research and government reports state that inappropriate use of drugs by both prescribers and the public is widespread in every part of the world. There is concern about adequacy of the practical prescribing skills with which medical students begin their professional lives, the bad examples frequently offered young doctors by senior colleagues, and how adequate evaluations of the enormous range of drugs currently marketed can be made by a busy prescriber, who may have little medical school at a time when clinical pharmacology was not even an established discipline (see interview with Professor Patrie on page 16).

Australia is tackling these and many other problems related to the drug sector. An overall strategy was needed, the government decided, and established a representative advisory council of all major players. By 1992 three arms of a drug policy were in place covering quality assurance, equity of access to medicines and local industry development. But it became apparent that a critical aspect was missing, namely the link between these three elements and health outcomes. A separate committee, the Pharmaceutical Health and Rational Use of Medicines (PHARM) Working Party was therefore set up to advise on a strategy for appropriate drug use. Members share skills in health education, research, behavioural science, specialist and general practice, community development, nursing and pharmacy. As Dr Mary Hodge, chair of the group, reports on page 12 this created an opportunity to share different ways of thinking and facilitated new approaches by drawing on experience from a variety of disciplines.

The Australian approach of interlinked, clearly articulated policy development and implementation - with its major focus on the appropriate use of drugs - goes far beyond the more typical control mechanisms limited to governing drug production, marketing and prescribing. It calls for a "partnership between consumers, health professionals, government and industry", in which "appropriate and effective education of all groups, the development of innovative models of practice and the investigation of options to overcome structural and other operational constraints, are key strategies." It asks all practitioners at every level to use their skills, knowledge and resources to develop good working relationships and an environment which enables medicines to be used wisely and safely. Dr Hodge reports that although the partnership developed so far between groups is fragile, continued dialogue and experience in working together show signs of significantly improving mutual understanding of responsibilities and constraints.

Future drug policy development in Bangladesh and Australia will receive close scrutiny. In Bangladesh, there will be concern that policy successes are built upon and publicized, while areas in which implementation has been weak are strengthened. For the developed countries, the Australian approach may provide some answers to questions concerning their need for and the benefits that may accrue from a clearly articulated and coordinated national drug policy. Interestingly, the development of national drug policies is an area in which the developing world is leading the developed. Western countries can no longer be sanguine that the uncoordinated policies, lack of public accountability, and unequal relationships among partners - at present all too prevalent - will be sufficient to govern adequately the increasingly complex pharmaceutical sector and ensure that public health considerations adequately balance economic and other factors in policy making.
Drug costs and consumer rights

W hen cost can have an effect on the choice of medicines available to the consumer, or the selection of one drug over another, then the cost considerations should be made clear to the patient, according to Anna Bradley, deputy research director of the UK Consumers' Association.

Speaking at the Drug and Therapeutics Bulletin's recent symposium "Drug Costs and Treatment Choices", Ms Bradley noted that the patient now has to face the issue of health care costs because of the changes in the UK National Health Service and the way in which drugs are available to the patient, i.e. some drugs are cheaper over the counter than on prescription. Patients as consumers have begun to make more demands, particularly for information on, and participation in, decisions made about their health and the cost of health care.

With doctors being encouraged to prescribe generically, parallel importing, and the proposed extension of the selected list scheme, more patients will see changes in their medication, and want an explanation, Ms Bradley said. They need "adequate information about the comparable efficacy of drugs in question and the simple statement of fact that costs are then a consideration", she argued.

Source: Ser vice, April 1993.

World Health Assembly calls for action to protect INNs

T he system that identifies each pharmaceutical substance included in marketed pharmaceutical products by a unique, universally recognised generic name is of crucial importance to international communication in medicine. WHO's programme on the selection of International Nonproprietary Names (INNs) is intended to maintain and protect this system, and since 1950 names have been selected for approximately 6,000 pharmaceutical substances.

The procedure for selecting INNs allows manufacturers to contest names that are either identical or similar to their licensed trade marks. In contrast, trade mark applications are disallowed only when they are identical to an INN. Because of the competitive promotion of products no longer protected by patents, INNs now require greater protection. Rather than marketing such products by generic name many companies apply for a trade mark derived from an INN and, in particular, including the INN common stem. The 1991 WHO Expert Committee on the Use of Essential Drugs warned that "this practice endangers the principle that INNs are public property, it can frustrate the rational selection of further INNs for related substances and it will ultimately compromise the safety of patients by promoting confusion in drug nomenclature'.

It was against this background that the Forty-sixth World Health Assembly in May 1993 adopted a resolution drawing attention to the dangers inherent in the situation and calling for action. The resolution acknowledges the fundamental contribution of international nonproprietary names to effective communication in medicine, and expresses satisfaction with the increasing contribution of generic products to national drug markets in both developed and developing countries. However, it warns that the current trend to market generic products under trade marks or brand names derived from INNs may compromise the safety of patients by creating confusion in prescribing and dispensing medicines and by interfering with the orderly development of the nomenclature for INNs.

The resolution calls on Member States:

- to enact rules or regulations, as necessary, to ensure that international nonproprietary names (or the equivalent nationally approved generic names) used in the labelling and advertising of pharmaceutical products are always displayed prominently;
- to encourage manufacturers to rely on their corporate name and the international nonproprietary names, rather than on trade marks, to promote and market multisource products introduced after patent expirations;
- to develop policy guidelines on the use and protection of international nonproprietary names, and to discourage the use of names derived from INNs, and particularly names including established INN stems as trade marks".


French prescribing

D ata released by the French health insurance agency, the CNAMTS, reveals that many doctors are prescribing wastefully, and in some cases carelessly (see EDM-14). The figures are likely to give impetus to government cost-containment moves, noted Ser vice, April 1993.

At a recent meeting in Paris, a number of studies were presented suggesting that if doctors prescribed more frugally, patient care would be improved, health care costs would be lower, and "enormous waste" could be avoided. Older studies suggested that for many prescriptions written for patients over 60 years of age there was a high risk of drug interactions.

In the Vendée, the prescribing of antibiotics by doctors seemed to be "medically useless". In 45% of cases (out of 200), while in Amiens, doctors prescribing broad-spectrum antibiotics for no reason did not respect medical prescribing rules in 50% of cases, according to the CNAMTS. Gilles Jouhanet, director of the CNAMTS, said that the situation was "worrying" and that it was even more necessary now to press forward with discussions on containing health care spending.

Doctors at fault?

A recent report from Robert Launois, professor of health economics at the Bobigny Faculty of Medicine, concluded that doctors do not pay adequate attention to the consequences of their prescribing, and that the scientific rigor of their choices was often questionable. The high level of prescribing of antibiotics was reported in the report as a particular problem.

There are moves to set up a special research centre, attached to the health economics research institute CREDES, where health professionals, insurers and industrial health service managers exchange information and experiences in the areas of health care economics and rational prescribing.
The Baltic States: new project promotes rational drug use

Until that is in place, Latvia is burdened with an inheritance of thousands of licensed drugs about which they have little or no information. The Latvian drug regulatory agency has a list of 3,000 drugs which were manufactured and licensed in the name of the former USSR. The only data available is the name of the drug (in Russian) and the licence number. A large number of imported drugs are also licenced without sufficient information about how to use them. All of these drugs are now provisionally licensed in Latvia until 1994. Because of concern about the safety and the quality of such drugs, the Latvian Government is currently reviewing this list.

Latvian essential drugs list

Latvia has drawn up an essential drugs list which is used as a guide for pharmacies to build up their stock. A visit to a few pharmacies caused some doubt about the extent to which this list is used, particularly by the so-called hard currency drug stores, which prominently display expensive brand name drugs. For example Loperamide, an anti-diarrhoeal drug, was widely available for $6 a package, the equivalent of half a month's minimum wage.

Sad as a pensioner in a drug store

The high price of drugs is a major problem, particularly for the elderly. Many groups of people receive free drugs. This includes small children, pregnant women, people who worked around the Chernobyl nuclear site, handicapped people, ex-political prisoners, and patients after major surgery. The cost of drugs for these patients comes out of the hospital budget, which puts a great burden on the hospitals' finances.

The challenge for Latvia is to build a system of drug regulation that ensures the appropriate supply of the drugs that are needed. Latvia is rapidly moving away from the old, centrally controlled health system. At the same time, the health authorities realise that control of medicines is essential.

Control medicines before they control you

Many groups expressed the need for information about drugs. Almost no information about drugs was available. Medical students are only beginning to learn about the principles of rational prescribing and doctors often have to choose from a collection of obsolete and bad quality drugs without adequate product information.

For more information on all the project's activities, contact: HAI-Europe, Jacob van Lennepkade 334 T, 1053 NJ, Amsterdam, The Netherlands.
EC pharmacists to lobby for substitution

One of the main priorities of Joao Silva, the new president of the EC pharmacists' representative body, the Pharmaceutical Group of the European Community (PGEC), is to promote substitution by pharmacists of cheaper products throughout Europe. Dr Silva says that substitution, which is already allowed in a number of European countries, should be permitted in all of them, according to Portuguese reports. He believes that pharmacists should be allowed to dispense the cheapest available multissuer product, no matter what it is called, according to Dr Silva. He recognises, however, that substitution will not be accepted overnight by all member states - the recommendations made last year by the European Commission in this area were opposed by the pharmaceutical industry and doctors.

Other measures

In a document outlining its plans for 1993-94, the PGEC, which represents pharmacists' associations in the 12 EC member states, says that it plans to keep up its lobbying activities and increase contact with its national delegations. Other projects include: developing a PEGC database with legislative and economic data on health, pharmacy and medicines in Europe; looking at and drafting Good Pharmacy Practice proposals; monitoring developments in the self-medication field; in collaboration with the AESOP (European OTC Manufacturers' Association); setting up a working group to look at ways in which to provide pharmacists with information to facilitate drug selection; promoting training for pharmacists; and establishing relationships with pharmacists in Eastern and Central Europe.

Dr Silva, who has been on the board of the Portuguese pharmacists' association, ANF, since it was set up in 1974, was appointed president of the PGEC on 5 February, replacing Dimitrius Vagianas, who becomes vice-president.

MaLam network continues to expand

The Medical Lobby for Appropri- ate Marketing (MaLam), an international non-profit membership organisation for health professionals, has now established affiliated national associations in Sri Lanka and the Netherlands. MaLam's aim is to encourage drug companies to provide sufficient, consistent and accurate information to enable correct prescribing, dispensing and consumption of drugs. In Sri Lanka, Students Involved in Rational Health Activities (SIRHA) will distribute MaLam's monthly literature, and initially subscriptions will be free.

15-country study on the use of the WHO Certification Scheme

In September 1992 DAP convened an informal consultation on how to improve WHO assistance to drug quality assurance systems in developing countries. The outcome was a decision to conduct an independent assessment of the operation and effectiveness of the WHO Certification Scheme to determine how it could be most effectively promoted and used. An initial study protocol was reviewed in April, at a preparatory meeting in Kenya, with an international team of researchers who will work with local counterparts in each participating country. Field work, now underway, covers 15 countries in the Africa, American, Eastern Mediterranean, South-East Asia and Western Pacific Regions. Data and a summary report should be available by early 1994.

Where's the prescription?

European developed country pharmacists dispense drugs without a prescription! In Italy, a consumers' team found that 14 pharmacies out of 100 in major cities dispensed a hypnotic drug without a prescription. In three out of ten cases, the client was given products which are strictly prescription only; of the 14 pharmacies where triazolam was given on request, only six gave warnings about the use of the product, reports Scrip, 1 December 1992. Some sold analogues such as ketoprofen, or antibiotics for diarrhoea containing bacitracin plus neomycin, without a prescription. Half the analogues or antibacterial products dispensed by the pharmacists were described as "unsuitable" by the report. According to the Health Minister the problem lies with the professional attitude of pharmacists who may have reasons for dispensing one product rather than another. "The incentives offered by pharmaceutical companies can be very tempting", he observed.

Essential Drugs Action Programme a priority

Meeting at WHO in Geneva on 23 to 25 February 1993, the Management Advisory Committee of WHO's Action Programme on Essential Drugs reviewed the activities of 1992 and approved a US$28 million budget for 1994-95. The programme, representing 25 countries, a dozen international and non-governmental organisations and the pharmaceutical industry, applauded WHO's reaffirmed commitment to the promotion of essential drugs as a means of improving health care and establishing greater social equity.

The Committee was informed that 64 developing countries now had their own essential drugs programmes and that 28 others were in the process of developing such programmes. Nevertheless, drugs remained inaccessible to many people throughout the world, despite their importance to adequate health care. No disease control programme can be effective if the overall drug infrastructure is weak and if a national drug policy does not exist, participants were told.

The Committee heard reports on the Action Programme's operational activities, including its wide ranging support to countries throughout the world in the development of national drug policies, essential drugs programmes, quality assurance, legislation, education and training. The Programme also had a significant research and development component, members were told, and had recently identified priority areas of work which included indicators of national drug policy and the world drug situation; experience gained in methodologies to improve prescribing practice; studies on self-medication; a review of public education programmes, and an analysis of the impact of privatisation on drug availability, accessibility and use.

African regional meeting on essential drugs in Brazzaville

Pharmaceutical policy makers have important experience to share concerning the policy development process, content and monitoring, particularly regarding common regional problems.

In order to draw on this pool of knowledge, representatives from Benin, Burundi, Guinea, Malawi, Nigeria, Sudan, Tanzania and Yemen met in WHO's Regional Office for Africa for two weeks in April to discuss policy making issues and to draft a common methodological approach.

The outcome of the meeting was an outline for two practical guides: the first covering the formulation and implementation of a national drug policy; the second dealing with the development of a pharmaceutical master plan. A report of the meeting and the two manuals will be issued by WHO later in the year.

Thailand increasing consumer awareness of drugs

As part of its programme on Consumer Education on Pharmaceutical, the Thai Drug Study Group recently convened three seminars, reports HAI News. The first of these, "WHO Ethical Criteria on Medicinal Promotion and the Thai Situation", enabled doctors, pharmacists and medical detailers (drug representatives), to discuss prescribing practices, pharmaceutical promotion, and the role of detailers in Thailand. Participants also developed strategies for promoting ethical criteria in drug promotion. Ethical advertising was also the focus of a second seminar attended by journalists and staff and students of pharmacy schools. Speakers described pharmaceutical promotion in Thailand and other areas of the world in the context of WHO's guidelines.

The final seminar in the series was organized by the Coordinating Committee for Primary Health Care of Thai NGOs and the Drug Study Group, to discuss the Thai Patent Law and the concept and implementation of a Genter Act for which the NGOs have been campaigning.

A pharmacy in Thailand where consumer education on drugs is growing.
Pakistan: irrational drug use condemned

In February 1993 leading Pakistani politicians, doctors and representatives from the media attended a national workshop on the rational use of drugs for children and the role of the mass media.

As many as 12,600 drugs are sold in Pakistan, and speakers highlighted what they regarded as the apathy of government agencies in allowing the use and sale of irrational and ineffective medicines. Delegates agreed that responsibility for the problem also lay with the multinational pharmaceutical companies, doctors and the parents of sick children.

The workshop was organized by Health Action International, Pakistan, the Pakistan Paediatrics Association and the Nepal Network for Rational Use of Medication in Pakistan, in collaboration with the International Organization of Consumers' Unions.

It concluded with an agreement to campaign at policy level and also to begin a popular education programme on the issues involved. Participants also called for a major media effort to persuade people that they do not need to take drugs for every minor ailment.


New rules for pharmaceutical advertising in Mauritania

A new decree to control all aspects of pharmaceutical promotion has been issued by Mauritania's Ministry of Health.

According to the decree, all information relating to the properties of a pharmaceutical product must now be "reliable, precise, truthful, instructive, balanced, up-to-date and justifiable."

There can be no omissions which could lead to unjustified use of a product. Each advertisement must list the dosage, indications, possible risks, required precautions, contra-indications and adverse reactions, as given in the application for the product's marketing authorisation. In addition, all new promotional materials in the country must be approved by the Director of Pharmacy and Medicines before being issued.

More than 50 professors and staff from 13 medical and pharmacy schools attended a national universities workshop which focused on national drug policies, rational prescribing and its teaching at Iran's universities.

After three days of group presentations and discussions, participants called for the preparation of a written national drug policy statement, endorsed by all parties involved and summarised in the national health policy. The national essential drugs list should be regularly updated and mechanisms put in place to facilitate this. Clinical pharmacology and rational therapeutics should be re-introduced as part of the medical curricula and the disciplines of hospital and clinical pharmacy strengthened. Finally, all teaching hospitals should develop hospital formularies and departmental prescribing policies, with clinical pharmacologists and relevant clinical specialists closely collaborating in their development.

The success of the workshop, held in December 1992, was confirmed by the decision to hold two similar ones to include the remaining 21 medical and pharmacy schools in other regions of Iran.
American campaign against antidiarrheals

A petition by Public Citizen, a US consumer advocacy organization, calls on the US Food and Drug Administration (FDA) to ban or relabel five of the most common prescription and over-the-counter drugs used to treat diarrhoea in children. The petition is a result of a WHO report that these drugs are ineffective and may be harmful to children.

Worldwide, an estimated four million children under the age of five die each year as a result of diarrhoea, with dehydration the main cause of death. The consumer organization stresses that most child deaths could be prevented by oral rehydration therapy (ORT), which is simple but highly effective. ORT uses a mixture of fluid, sugar and salts, either commercial or home-made, to dramatically reduce diarrhoea related deaths. Usually no other medication is required, as drug treatment is only needed in approximately 5% of cases of diarrhoea.

Public Citizens argue that if the FDA acts to deregister some or all of the products named in the petition, which include paracetylmetharbulate and atropine, they can no longer be exported to developing countries, where the cost of such unnecessary medications is an additional "side-effect". More importantly, the inappropriate use of drugs often delays or replaces appropriate diarrhoea treatment. Giving the reason for the organization's actions, Dr Sidney Wolfe of Public Citizen, said, "The tragic toll of acute diarrhoea could be avoided with proper treatment, built around the use of oral rehydration therapy, rather than the largely useless and often dangerous drugs described in the petition."

For more information contact: Public Citizen, 2000 P St, NW, Washington DC, 20036 USA

US President attacks drug prices

PRESIDENT Bill Clinton has criticized the price of prescription drugs as "shocking" and blamed "vaccine makers for pursuing "profits at the expense of our children". In a hard-hitting speech he said that "the pharmaceutical industry is spending US$1 billion more each year on advertising and lobbying than it does on developing new and better drugs. Meanwhile, its profits are rising at four times the rate of the national average. Fortune 500 company (America's most profitable companies). Compared to other countries, our prices are shocking. The profit in the US currently costs close to US$10. In England, the same drug is available for US$4.80. In Belgium, it costs 77 cents. The problems of having an adequate delivery system, plus the spiralling costs, are putting America's children and America's future in jeopardy," the President said.

According to a Senate report in 1991, several popular brand-name products increased their prices by well over 100% during the previous five year period. Many Americans, who typically must pay 35% of the cost of prescription drugs themselves, have been flocking to Mexico for pharmaceutical bargains. The country's pharmaceutical industry, America's most profitable manufacturing sector, has responded with news- paper and magazine advertisements proclaiming the benefits of their products. Recently, many drug companies have started to cut their costs and moderate their prices. At the same time, health maintenance organizations have begun buying in bulk and demanding the most cost effective medications.

Experts say that America's drug prices could be better controlled if doctors paid more attention to drug costs and patients had access to information that would enable them to compare drug prices.

Drug prices: IOCU asks why they differ so much?

ACCORDING to Dr K. Balasubramanian, pharmacological advisor in the International Organization of Consumers Unions (IOCU), "Enormous variations in drug prices do not seem to fit into any pattern, varying arbitrarily from country to country."

Citing the results of an IOCU pricing survey which compares the retail prices of a limited number of widely used essential drugs in 11 countries, Dr Balasubramanian highlighted the random nature of pricing policy. He pointed out that while Tanzania recorded the highest prices for generic cimetidine, it had the lowest for ampicillin and methotrexate. In India, cimetidine costs less than anywhere else, yet it has the second highest price for methotrexate, and erythrocyte costs twice as much in Bolivia as it does in Britain.

The study makes it very clear that market forces by themselves are unable to regulate the price of drugs and provide safeguards to the consumer, Dr Balasubramanian claimed. He called on developing countries to regulate drug prices by implementing appropriate pricing policies which had "social justice and equity of access to all sectors of the population to at least the essential drugs".

Dr Balasubramanian concluded by recommending a possible option for developing countries wishing to promote rational and economic prescribing and use of drugs. These include introducing limited lists and therapeutic guidelines for common diseases; legislating to allow generic substitution; increasing cost effectiveness of drugs in medical education; publishing a national formulary including drug prices; and implementing a policy to inform and educate consumers on health and pharmaceutical matters.

ARC launches rational use newsletter

The Arab Resource Collective has produced the first issue of its newsletter Arab Therapeutics. Aimed at providing updated and non-biased information on drugs, the newsletter will be distributed to individuals working towards rational drug use in the Arab world. It provides a forum for the exchange of ideas, experiences and information among those working in the field of rational drug use in Arab countries, with the ultimate goal of establishing an Arab network for the rational use of drugs.

Medical education for primary health care

The essential drugs concept and its inclusion in pharmacology training were two of the main themes of a workshop held in New Delhi in December 1992. Speakers from the Karolinska Institute, Stockholm and WHO's Collaborative Centre for International Drug Monitoring joined local participants in discussions on good prescribing practice, adverse drug reaction monitoring and methods of disseminating drug information.

The workshop, part of the country's Continuing Medical Education Programme on Clinical Pharmacology, contributed with recommendations on systematic training for clinical pharmacologists, the need for a central drug information centre and organized adverse drug reaction monitoring.


A routine malaria survey on the island of Grand Comore to obtain the seasonal malaria parasite rates amongst school children

The challenge of controlling malaria

MALARIA has a profound social and economic impact and currently claims one million lives a year. Almost half the world's population are at risk from the disease. Far from improving, the malaria situation worldwide is deteriorating compared to 10 years ago. The spread of drug resistance, population movements and ecological disturbances are all contributing to increased incidence of the disease. In view of the gravity of the situation, WHO convened a global malaria conference, to raise public awareness of the disease and to stimulate action to curb it.

The conference, held in Amsterdam on 26 and 27 October 1992, was addressed by the ministers of health of other senior health leaders of 65 countries in which malaria is endemic. The discussions highlighted, these countries share many common problems in controlling malaria. These include, population growth and low educational levels, inadequate development of primary health care, lack of financial and managerial resources, insufficient knowledge about essential antimalarial drugs, and a lack of community participation in health protection and promotion.

At their meeting, the ministers issued The World Declaration on the Control of Malaria, endorsing a global malaria control strategy to: provide early diagnosis and prompt treatment; plan and implement selective and sustainable preventive measures; detect early, contain, or prevent epidemics, and improve local provision for basic and applied research. Participants committed themselves and their countries to malaria control as an essential part of health development, involving communities as well as sectors concerned with education, agriculture, sanitation and development as partners.

The conference called for an international effort, coordinated by WHO, to implement control in the context of primary health care, seeing it as an opportunity to strengthen health and social structures. It also endorsed the fundamental right of all populations to early diagnosis and appropriate treatment for malaria, especially in the least developed countries where the challenge is greatest.


**Essential Drugs Monitor**

**NEWSDESK**

**International conference on essential drugs for French-speaking countries**

The first international conference on essential drugs in French-speaking developing countries, organized jointly by the Faculty of Medicine of the University of Grenoble and the World Health Organization (WHO) was held in Grenoble, 7-9 June 1993, under the patronage of the French National Academy of Medicine. Attending the conference were officials from ministries of health, health professionals, from faculties of medicine and pharmacology, the pharmaceutical industry and consumers from some 20 different countries. The principal objective was to determine methods to place safe and effective drugs at the disposal of developing countries at the cheapest possible cost and to promote their rational use. The key element for a successful and sustainable essential drugs policy is the close cooperation of the principal sectors represented at Grenoble, underlined Professor Pierre Ambroise-Thomas of the University of Grenoble Faculty of Medicine and a co-organizer of the conference. The chain of participants stretches from WHO to the health workers in a tiny dispensary miles from anywhere, with all that this implies, such as the training of prescribers and rational drug management, he said. Conference topics included:

- pharmaceutical policies based on the concept of essential drugs;
- the importation and production of essential drugs;
- drug management and regulation;
- essential drugs and tropical diseases research and development;
- the teaching role of universities.

Participants concluded by unanimously affirming their commitment to pharmaceutical policies based on the essential drugs concept and called for:

- incorporation of the essential drugs concept into the training of doctors and health care professionals;
- development of a real partnership between public authorities, academic institutions, the pharmaceutical industry, NGOs and international organizations, in order to implement pharmaceutical policies based on the essential drugs concept;
- research into prevention and treatment of tropical diseases, notably by encouraging cooperation and complementarity between public and private research;
- continuation and development of the work began during the Grenoble conference by holding regular meetings, and through a WHO global conference.

A report of the conference will be issued by the Faculty of Medicine of the University of Grenoble, Université Joseph Fourier, Domaine de la Merce, 38706 La Tronche Cedex, France.

---

**LETTERS TO THE EDITOR**

**Using herbal remedies wisely**

I read with interest "An interview with the Minister of Health of Nigeria" (EDM-12) and more recently a "Letter to the Editor" from Dr E. Gule, Australia (EDM-13). They draw attention to the problems encountered by physicians in the practice of what is known as traditional medicine, especially in developing countries, which in many countries are not on the market without adequate prior clinical trials or pharmacological studies to ensure their safety. A recent article by Montes (1987) discusses deaths resulting from toxic use of the leaves of Senecio fistulosus a Chinese plant, common name “hualatia” or cow’s tongue. D’Arcy (1992) writes on various herbal medicines which are hepatotoxic, in some cases lethally so. Fairboth (1992) reports two cases of poisoning with aconite preparations, showing the high toxicity of this Chinese herb. There are many other articles on the toxicity and misuse of various herbs. I am not setting out to praise or criticize such drugs, since in China there is still no clear policy on medicinal plants, much less on other types of traditional medicine. However, like Dr Gule, I would remind readers of the care that should be taken with medicinal plants, which are sometimes used indiscriminately, even though our ancestors for many generations used them against illness.

In any event, we are the beneficiaries of that ancient knowledge, which forms the basis of modern phytotherapy. It should be borne in mind that medicinal plants have been used and will continue to be a vital source of new, natural products that will provide new drugs for people in years to come.

In the Americas the greatest and most important influence is that of the indigenous medicine of each country, which some authors describe as “popular medicine”.

Józef L. Martínez, Departamento de Farmacología, Facultad de Medicina, Universidad de Chile, PO Box 70 000, Santiago 7, Chile.

References:

---

**Telephone advice for the Swiss**

In EDM-14 you published an article about a telephone drug advisory service in Switzerland. Do you have any further information about this service?

Isabelle Schmidt, Medical Department, SmithKline Beecham Pharmaceuticals, Thörishaus, Switzerland.

We have had several enquiries on this subject. Anyone wishing to contact the Swiss Drug Information Office can telephone on Tuesday or Friday afternoons between 14.00 and 18.00 on 156 65 54 (from within Switzerland) and +61 692 8711 (from outside Switzerland). Alternatively you can write to Schweizerische Medikamenten-Informationsstelle, Postfach 124, 4007 Basle, Switzerland, Ed.
RESEARCH

A new study could help women avoid risk after childbirth

The study found that the stability of injectable ergometrine is a widespread problem. In only 29% of field samples taken from six tropical countries did the level of active ingredient comply with US and British Pharmacopoeia (USP/BP) limits of 90%-110% of the stated content, while 28% of samples contained less than 60%. No field data on methylergometrine were available. The few field data on oxytocin suggest that by the time the product is used, the quality is generally acceptable, mainly because many products contain more active ingredient than the stated amount.

A study conducted in 11 batches of injectable ergometrine, methyl-ergometrine and oxytocin under different conditions of temperature and light showed that there is no difference in stability between ergometrine and methyl-ergometrine other than differences between batches. These differences can, however, be considerable.

When kept under refrigeration for 12 months, the eight sets of gender and its level of active ingredient (±0.847% for ergometrine, ±0.873% for methyl-ergometrine). Any discoloration of (methyl)ergometrine of good initial quality, i.e. any discernible difference between its content and that of clear water, indicates (with a sensitivity of 97-100%) that the level of active ingredient is below USP/BP standards of 90% of the stated content, and that it should not be used. When this rule is applied, about 6% of colour failures are false positives. The solution should be compared with clear water in identical glass tubes against a well-illuminated background.

The instability of some of the samples could not be related to an abnormal PH or the oxygen content of the initial solution.

RECOMMENDATIONS

Selection of injectable oxytocic for tropical climates

There is no difference between the stability of ergometrine and methyl-ergometrine per se, other than differences between brands. Oxytocin is more stable than methyl-ergometrine. The study shows that it is certainly more stable when exposed to light and that it is probably also more stable when kept in the dark, with or without refrigeration. As the difference between brands is an important factor, ergometrine and methyl-ergometrine should be precluded from reputable suppliers who supply all necessary documents in accordance with the WHO Certification Scheme for Pharmaceutical Products. Moving in International Commerce, and whose product is of proven quality and stability. Upon arrival in the country, or upon delivery to Central Medical Stores, each batch should be inspected. The most important thing is to check if the contents will be protected. The level of active ingredient should also be tested. Ergometrine and methyl-ergometrine delivered in clear glass ampoules should be rejected.

Storage

Injectable ergometrine, methyl-ergometrine and oxytocin should be stored under refrigeration. All products should be clearly marked "Keep under refrigeration", and ergometrine and methyl-ergometrine should additionally be marked "Protect from light". For most products, short periods of unrefrigerated transport are permissible. These should not exceed one month at 30°C or two weeks at 40°C.

In dispensaries and labour wards, ampoules of ergometrine, methyl-ergometrine and oxytocin should be kept under refrigeration and should only be taken from storage when absolutely needed. It is particularly important to avoid keeping ampoules of ergometrine and methyl-ergometrine in open trays, as this reduces the level of active ingredient by about 21-27% per month. If refrigerated storage is not available, temporary storage outside the refriger scarcely acceptable for most products for a period not exceeding three months. Nevertheless, exact recommended storage conditions for a particular brand may differ from the above recommendations, because, as we have noted, stability varies between brands.

Identification of ampoules with low levels of (methyl) ergometrine

Before being administered to the patient, every injection of (methyl) ergometrine should be visually checked by the health worker. If the solution does not look like clear water it should not be used. In addition, staff responsible for the quality of drugs (e.g. hospital pharmacists) should regularly check on the colour of the injectable (methyl) ergometrines in stock, by carefully comparing the product with clear water. 

Sample taking for the stability study in Masvingo Health Centre, Zimbabwe

A squared reporte which was used in the study. It can record temperature and relative humidity every 3 hours for 10 days (Battery powered)
A new approach to advising mothers on diarrhoea

Third, the process will help the health worker to focus on what the mother already does and knows.

Advising Mothers is a training tool which, ideally, should be used during a clinical management training course. It may also be used as a "refresher course" for health workers previously trained in clinical management (although the cost of holding a special workshop may be prohibitive). Based on experience in a number of countries that have used Advising Mothers, sample agendas have been developed for integrating the skills and exercises into clinical management training. These are available on request from WHO. On average the exercises require about eight hours. If the guide is incorporated into clinical management training, practice on advising can take place during regular clinical practice sessions. If advice training is carried out separately, an extra half day will be needed for clinical practice.

Any future revisions of clinical management training materials will include Advising Mothers as part of standard training. Until the revised materials are available, Advising Mothers will be available from CDD as a separate document. National CDD programmes should envisage incorporating Advising Mothers, suitably adapted, into clinical management training for all levels of health personnel.

For further information write to: World Health Organization, Diarrhoeal Disease Control Programme, 1211 Geneva 27, Switzerland.

Care for your child's diarrhoea

- Give your child more than usual to drink: Good drinks are...
- Continue to breastfeed
- Encourage your child to eat soft, mashed foods: Good foods are...
- If your child...
  - is very thirsty
  - has blood in the stool
  - has many watery stools
  - vomits many times
- ...take the child to the health centre

---

1. Ask questions:
2. Praise and encourage the mother's helpful practice;
3. Advise the mother what to do (and why);
4. Check that the mother understands;
5. Refer the mother to a group session if necessary.
NATIONAL DRUG POLICY

The future of the Bangladesh national drug policy

Andrew Chetley

Bangladesh was the first country to develop a policy based on internationally accepted public health concepts such as primary health care and the need for essential drugs. In June 1982, Bangladesh introduced a National Drug Policy (NDP) and a Drugs (Control) Ordinance. The main objectives of the NDP were to:

- increase availability and accessibility of good quality essential drugs;
- eliminate useless, non-essential and potentially hazardous drugs from the market (this was taken to include allopathic, homeopathic, and traditional Ayurvedic and Unani medicines);
- encourage local manufacture of drugs and raw materials, particularly essential drugs; and
- develop appropriate legislative and administrative mechanisms.

The Drugs (Control) Ordinance provided the legislative framework for the NDP and also allowed the government to fix maximum prices for the import or sale of raw materials and for the retail sale of finished drugs. The NDP led to the selection of 250 essential drugs (now 320) and to the banning of 1,666 products that were useless, ineffective or harmful.

Drug policy success

Over the past decade, the Drug Policy has gone some way towards meeting many of its objectives. These achievements include:

- increased local production of essential drugs;
- stable drug prices;
- greater price control by national companies;
- less dependence on imported products and imports;
- less waste of resources on non-essential or useless products; and
- an improvement in the quality of drugs.

More essential drugs

The value of local production of drugs has increased by more than 217% in local currency terms. The production of essential drugs has also increased from 30% of local production in 1981 to 80% in 1991. This has been described as “the number one achievement of the drug policy”.

Stable drug prices

Raw material prices have been dramatically reduced. Retail prices, too, have been held down. Between 1981 and 1991, the retail price of 25 major drugs has increased an average of 20% in local currency, but has declined by more than 40% when the prices are converted to US dollars to take into account inflationary effects. Compared to the consumer price index, which rose by 173% (in local currency) during the same period, real prices have become more accessible and affordable to people in Bangladesh.

Bangladesh companies gain a bigger share

In 1981, eight multinational companies controlled 65% of the local production and about 75-80% of total sales, including about 80% of sales to the government sector. By 1991, Bangladeshi companies controlled more than 60% of the local production, with one national company supplying about 70% of the government sector’s drugs requirements.

Decreased dependency and increased savings

Prior to the NDP, half the drugs considered essential for public health were not being manufactured in Bangladesh. In 1981 one-third of the import bill was for finished drugs, but in 1991, it was less than one-eighth.

The import statistics, however, do not show what might have happened if there had been no Drug Policy. If dependency on imported drugs had continued over the past 10 years, an additional USS 1.4 million would have been required to pay for the imports of finished drugs.

As well, in 1981, about one-third of all production went on useless products. If there had been no Drug Policy and this unnecessary production had continued, more than USS 436 million would have been wasted. In total, then, the NDP has saved the country and its people more than USS 20 million.

Better quality

Drugs tested over the years by the national Drug Testing Laboratory (DTL) show an improvement in quality. In 1981, 36% of samples tested were substandard compared to only 9% in 1991. There is, of course, still considerable room for improvement.

The policy today

Despite these successes, the NDP has come in for criticism over the years. Much of the criticism has come from the industry and from the medical establishment in the country, both of which feel that they were not adequately consulted about the NDP. The government has now appointed a committee whose composition reflects about which drugs are worth using. Many of the drugs being smuggled are those with a potential for abuse rather than essential medicines that are needed to improve health.

No access to life-saving drugs?

The Drugs (Control) Ordinance allows for the registration of products on the basis of their “safety, efficacy and usefulness”. Some physicians and company executives argue that this deprives patients of the latest life-saving innovative products that are being sold in other countries. However, any drug can be registered provided those criteria are met. In exceptional cases, special dispensation can be granted urgently for the importation of a new product for a named patient.

Too many restrictions?

Another argument is that limitations on products should apply only to the government health sector and that the private sector should be free of any controls on the drugs that can be sold. With the public sector covering, at most, 40% of the country’s health and medicine needs, such a position is unworkable. Policies applied only to the public sector rationalise but a smaller proportion of the drugs market.

Another approach to the private sector question comes from the industry argument that some “home remedies” should be allowed to “relieve symptoms and provide comfort to people”. Many of the products the industry hopes to get onto the market in this way are the “ineffective and useless medicines” that wasted people’s money before the NDP. This goes against both the spirit and the letter of the NDP to the public interest in the best interests of public health.

Excessive price control?

The industry argues that price control is excessive and should be scrapped. However, most company officials do accept that the control on the price of imported raw materials has been beneficial and is acceptable. Most of the debate focuses on the retail price which, it is claimed, does not allow sufficient margins for future investment nor does it provide an incentive or reward for quality. Some flexibility in the price controls may be necessary.

A fair deal for multinationals?

The NDP prevents multinational companies from manufacturing anesthetics and vitamins, does not allow licensing agreements if the same or similar product is available or manufactured in the country, and prevents companies that do not have a factory in the country from leasing spare capaci...
No quality control?

Most studies carried out on quality control in Bangladesh indicate that the companies at the bottom end of the market have the most problems with quality. The issue here is not so much with the NDP, which is clear about the need for quality drugs, but with the inspection and enforcement mechanisms that need to be strengthened.

Towards the future

In all the criticism of the NDP, there is no real substantive point that makes it obvious why the policy should be scrapped. The problems lie more with the lack of effective implementation mechanisms than with the NDP itself.

The policy issues regarding pharmacovigilance have been largely decided upon within Bangladesh over the past 10 years. The supply of medicines and assuring their quality is being worked on - too slowly for some, perhaps. But the principal question that still remains, the one that probably has the most bearing on health, relates to the rational use of medicines.

Among the factors that have a major influence on the rational use of medicines are:
- the national system of healing;
- the dispensers; and
- the quality of education about health and drugs.

Traditional medicine

The vast majority of people in rural areas seek treatment from unqualified allopathic or traditional healers. Traditional healers are powerful potential allies in efforts to improve the rational use of drugs. By training them to diagnose and refer, and by helping them to realise the role of medicines - whether allopathic or traditional - in health care, they can become positive forces for change within communities, rather than obstacles to good therapy, which is how they are often viewed.

Quality control. Traditional medicines has been described as varying from "awful" to "virtually non-existent". Some success has been achieved in removing the most harmful of materials, such as heavy metals, from the medicines, but more could be done. The underlying philosophy of traditional medicine is very different. By using only those herbs that are found to be safe and effective and by limiting combinations, a limited list of products could be developed.

Dispensers

In 1992, there were 20,000 licensed retail outlets for drugs. Unofficial estimates suggest that there are at least that number of unlicensed premises, plus an uncountable number of small shopkeepers and stallholders who have a few medicines along with their food products or cigarettes.

Most of the people running even the licensed shops are untrained. About 12,500 of them have had a short four-month training course that provided them with a certificate. A longer term strategy is needed for the situation in the future. A starting point could be no new issue of licences unless both the pre-requisite standards are compiled with and unless adequate training has taken place. Existing licences for pharmacies should be ended when the present owners die. Existing dispensers need to have intensive and regular training courses. Incentives should be given to those who attend courses and put into practice the training.

Health education

Several recent studies have found that the health workers' knowledge of the NDP, the essential drugs concept and the rational use of drugs is poor. Providing the general public and health workers at all levels of the health care system with continuous training and regular information are preconditions for rational drug use.

There are conflicting views in Bangladesh about the quality of education that prescribers receive, especially with regard to the rational use of drugs. Although the medical curriculum now places more emphasis on community health care that is appropriate to Bangladesh, this still needs strengthening. Various courses and training programs for doctors, nurses and grassroots level health workers have also been introduced by government departments and institutions, as well as by NGOs. Most of these training programs have emphasized motivation and commitment to primary health care.

Planning for the future

The problems that emerge in terms of the NDP, the rational use of drugs and general improvements in the health care system are broadly similar. We must include the absence of a formal national health policy, poor planning, the lack of an effective human resources development strategy, little accountability, weaknesses in training and education of health workers, little public education on health and rational use of drugs, and inadequate community involvement. The solutions to these problems are not easy, particularly when the country faces similar issues in other sectors. However, the programs operated by the government and by non-governmental organizations in several areas of the country have demonstrated that it is possible to tackle these issues.

While these are difficult challenges, the alternative - to simply let the health care system and the use of drugs evolve in an ad hoc manner - is to continue the same inequity and continued inequity. Bangladesh has been a pioneer in focusing attention on the essential drugs concept and on the need to develop a drug policy. It can continue this pioneering work by focusing now on the implementation of the policy, by putting the policy into practice more effectively.

Recommendations for action

To do this, several actions can be taken. Some are simple and straightforward, some require long-term commitment:

- having a regular review (every one to two years) of the list of essential drugs and to keep pace with pharmacological developments;
- ensuring that the committees that are part of the drug regulatory system have technically competent members, adequate servicing, and meet regularly.

From useless to essential drugs

- In 1981, one-third of all local production was devoted to useless, ineffective or harmful products. In 1990, only 16% of all local production was devoted to useless, ineffective or harmful products.
- In 1991, as a result of the National Drug Policy, 80% of all local production was directed towards essential drugs for primary health care.

Benefits for everyone

It is understandable that business has found the NDP "hostile", at times offensive, and certainly tough to live with. There will always be an uneasy tension between the health and business interests and the health concerns will have to remain the most important for some time to come. But business too can benefit from a focus on better health. Business has benefited from the NDP, as have health workers and the people.

By reviving its medical and pharmacy education and training, by improving education for consumers, by working more closely with communities to develop a health care system that meets the needs of the people, and by strengthening the regulatory and quality control mechanisms, Bangladesh can ensure that its people have access to the right drugs at the right price - and that they are used wisely.

- Andrew Chetney is a freelance researcher and journalist based in the UK. His book, From Policy to Practice - the Future of the Bangladesh National Drug Policy, on which this article is based, was reviewed in Essential Drugs Monitor No. 14. It is available from the International Organization of Consumer Unions, P.O. Box 1045, 10830 Penang, Malaysia. Price: US$8.

A village health worker discusses treatment. Continuous training is vital for the rational use of drugs.
Australia focuses on the quality use of medicines: policy and action

Mary Murray Hodge

A USTRALIA is a well developed country with low infant mortality and a high life expectancy among the white and multicultural population, but considerably higher infant mortality and lower life expectancy among the Aboriginal population. The population is 17 million living in a large geographic area but mostly concentrated in major cities.

By 1992, Australia had three arms of a drug policy in place:

- a system for regulating the marketing of quality, safe and efficacious products
- a national regulatory system to ensure the availability and safety of medicines
- an equitable access system for medicines by all Australians, that supply, stock and controls price

Consumers make a contribution towards the cost. This is known as the Pharmaceutical Benefits Scheme.

An industry development programme.

The development programme provides incentives to encourage companies to conduct more local R & D and value-added activity to domestic products and those for export to the region.

But what was missing was a rational drug use component which would firmly link these three activities to health outcomes. Awareness was growing amongst many organizations that it was not sufficient to have access to more drugs and a viable industry without equal attention to how the drugs were used.

Problems in drug use

A drug utilization committee established some years before had been building a data base to monitor national trends. Initial indications from this source and other studies were that:

- medicines are a part of everyday life for most Australians. Medication prescribed and bought "over the counter" is used by 76% of women and 65% of men at some time in a one-week period survey in 1987. A survey of people over the age of 65 years indicated that 90% were currently using medication.
- high consumption rates of medicines are associated with increased risk of therapeutic poisoning, part of which is preventable and due to inappropriate prescribing, non-compliance and inappropriate dosage regimes. The rate of admission to hospital due to therapeutic poisoning in the elderly doubled in one stage in the 10 years between 1981 and 1988.
- undertreatment of medicines is also of concern in the management of hypertension, asthma and vaccination regimes.
- safe storage of medicines to prevent childhood poisoning is still an issue.

As is wastage of medicines;
- there is no widely available objective consumer product information;
- a major area in reviewing the effects of drugs usage in Australia is that there are insufficient data, especially at the community level to assess the health, economic or social cost of sub-optimal use of medicines. Devisive studies are needed.

Developing a policy

In the light of these findings and concerns the government began to fund educational programmes but after two years realized that an overall strategy was needed. The Minister responsible was very committed to the issue, especially consumer education and community participation in the development of programmes. There was much to learn from past experience in implementing and administering the other arms of drug policy. This experience had been associated with an absence of caution, careful planning and animosity between players. This is probably inevitable during a period of the development of regulation and price control. While tough price control has resulted in low drug prices in Australia (60% of EBC average), it was found to have contributed to an environment that reduced the viability of industry operating in a small market. The entry of government into the domain of the patient-doctor relationship is new easy to manage. Any attempts to introduce policy or action which did not involve or adequately consult doctors and pharmacists in the process of decision making was likely to fail. Consumers had not traditionally been involved in the decision making processes. The signals from the past were that involvement of all players and communities were crucial. Individuals and groups from all areas, including health professionals, industry and government, had developed some initiatives in rational use over the years. Activities were largely uncoordinated and were not generally voluntary effort. Even in the case of consumers it was the consumers who were very instrumental in influencing thinking towards adoption of a formal notion, in fact, were at the forefront of the new drug policy. In 1990 the Minister formed two groups to advise him: the first was a council of formal representatives of organizations of the major players, which would raise issues and make recommendations across the whole gamut of drug policy; the second was the Pharmaceutical Health and Rational Use of Medicines (PHARM) Working Party to advise him on a policy for the quality of use of medicines and a strategy for its implementation. An internal Department of Health group was also formed to coordinate its own activities.

PHARM is a multidisciplinary and cross cultural expert group of consumer, industry, government and health professionals. They are just one of a wide range of consumer education strategies in Australia's drug policy.

Australia has also drawn on research in behavioural change and health education, exposed principles of community ownership, participation and consultation, and acknowledged the importance of media advocacy. It was at this point that the term "quality use of medicines" rather than "rational use" was adopted. While rational guidelines based on sound evidence and clinical relevance are crucial, PHARM also recognized that people's actions are strongly influenced by many irrational factors.

The group identified five key areas for action to improve the use of medicines:

- objective information for health professionals and consumers in the ethical promotion of medicines;
- education and training of health professionals and consumers;
- consumer services;
- provider services;
- education campaigns.

Approaches & strategies

This collaborative approach led in 1992 to the adoption by Australia of a quality use of medicines policy based on the work of PHARM. The policy endorses the WHO definition of rational drug use. Its goal is to optimise the use of medicines to improve health outcomes for all, while ensuring that the quality of medicines used and their cost are appropriate to the person and the condition being treated. Safe use of medicines means enabling people to take appropriate actions to solve medicine-related problems, thereby minimising misuse, underuse and misuse, encouraging safe storage and the avoidance of hoarding.

The approach being taken is:

- to use consumer and professional education as a primary tool but to address at the same time the structural issues, such as the organization of the health system and payment systems, which affect the ability of people to take appropriate action;
- to stimulate a partnership relationship between the major players, namely those who take, prescribe, dispense or make medicines, those who facilitate their use, monitor their effectiveness and efficiency, and those who provide equity of access to them;
- to identify:
  - what will empower consumers to use drugs well and health professionals to help them do this;
  - what constitutes effective education;
  - the combination of information, skills and motivation that will be effective for different groups;
  - what will work in practice;
  - what standards should apply and who should set them.

From policy to practice

Through various mechanisms of encouragement, including proactive consultation, target drugs for implementation and support for further development of existing programmes, initiatives for action are being established. Ideas from various groups are being identified. Activities present under way include:

Objective information:

The preparation of rational prescribing guidelines, a national formulary, consumer information and independent monitoring of drug advertising have been supported. An independent journal, the
Essential Drugs Monitor

Australian Prescriber, already exists. For the development of treatment guidelines for complex or controversial issues, consensus conferences have been held and another is planned later this year for hyper tension.

Control of advertising and promotion is regulated by a number of industry self-regulatory schemes. Government regulation also places restrictions on advertising. After a recent review by the Trade Practices Commission, the code of conduct for the prescription industry was revised. This revised code was unanimously adopted by members of the Australian Pharmaceutical Manufacturers' Association.

Education and training:
A schools kit for young children has been funded. For health professionals the process of developing a core curriculum in clinical pharmacology for all medical schools has been supported, as well as initiatives at the undergraduate and postgraduate levels which teach rational use of medicines within the context of the GP consultation. Clinical pharmacy training courses have also been supported.

Consumer services:
The development of medication record cards, innovative consumer education programmes to encourage consumers to ask more questions of their health professionals about medicines and to support them in running local campaigns on drug use have been developed.

Policy on Quality Use of Medicines

Major Components

Provider services:
Several types of academic detailing programmes have been developed, as well as a programme to increase the effectiveness of GPs' non-drug management of their patients' health at risk.
Programmes to improve drug use in nursing homes and to improve the communication about drugs between hospital and community care providers have been launched.

Education campaigns:
Two national education campaigns have been run in 1992. One aimed to educate health professionals and the community about the safety aspects of using non-stereoidal anti-inflammatory drugs and the changes made in the availability of these drugs on the Therapeutic Benefits Scheme. The other addressed general awareness about the risks and benefits of medicines and is described below.

The "Be wise with medicines" campaign
This was a major national community awareness campaign that used examples of community development and involved all players. 350 local community groups were given small grants to set up their own activities aimed to stimulate discussion and education of their members about medicines. Groups came from an enormously wide range of activities including health fairs, discussion groups run by their local doctors or pharmacists, and shopping centre displays.

Two community groups were trained members of other groups from all over Australia in the skills necessary to plan and conduct education workshops for consumers. The groups represented the old, young, a large number of multicultural groups and Aboriginal groups in metropolitan, rural and remote settings. Many developed their own material, in consultation with the campaign, or used campaign materials. Aboriginal groups developed certain materials in their own languages and a video to be used in remote communities by the Aboriginal health workers.

The campaign uncovered an enormous thirst for information and reflected Australia's changed cultural mix (since World War II). For example, a radio tape produced for multicultural radio was translated into 22 community languages. There were many requests for translation of medication record cards and fact sheets into other languages. The campaign worked with the professional groups to design materials and to encourage them to initiate discussion and review of medicines. A medication review consultation was developed for general practitioners with parallel guidelines for review and referral mechanisms for pharmacists and community nurses. A national phone-in was organized to have consumers' questions about medicines answered by a team of health professionals. The opportunity was taken to encourage consumers to ask their local doctor or pharmacist about their medication problems on a regular basis.

This strategy to dispense unneeded medicines was also tested.

Thus the community activities were designed to be complementary to the services that health professionals were encouraged to provide, such as answering questions, medication review, etc.

Bringing groups together
Two major workshops that brought together all major groups to discuss the areas of academic detailing and consumer education and information were extremely successful. This is seen as a very effective way of stimulating discussion between all groups for important issues. A workshop to explore issues in the use of the media in reporting medicines issues and in advocacy by all groups is planned for October 1993. In 1994, a workshop on nursing and the quality use of medicines will be held.

The future
The quality use of medicines is based on the close involvement of professional groups, which set standards and understand the needs and concerns of their members, and community groups, which understand the needs and concerns of consumers. A strong principle underlying the approach to optimizing the use of medicines is to stimulate new programmes and ideas while supporting existing effective initiatives within local communities or professional and consumer groups, wherever possible. A sustainable infrastructure is needed to facilitate, coordinate and support initiatives at state, regional and local levels in a way that honours this principle.

At the present moment, indicators and means of monitoring the use of medicines are being developed. A task force is working with industry, professional and consumer groups to carry out research with consumers on draft consumer information being developed by companies. The goal is to develop guidelines that will make the information as user friendly as possible. Consultation with a number of groups is in progress, this way with industry to discuss ways of developing good quality industry-sponsored education and promotion that contributes to the quality use of medicines and ways to discourage programmes that don't, with pharmacists to develop strategies to maximize their professional contribution to the area; with general practitioners to increase their use of medicines in the important changes underway that are restructuring general practice as a vocation and family health care; and with consumers to stimulate more community sponsored medicine use initiatives.

These initiatives are also being reflected in the work of Australia's aid agency, which assists the International Development Assistance Bureau has funded a number of projects dealing with the rational use of drugs in the Asia-Pacific region. It is currently working to clarify its further role to assisting developing countries in the region to meet their pharmaceutical needs.

The partnership so far developed between government and NGOs and industry is fragile. But continued dialogue and experience in working jointly on projects show signs of significantly improving the understanding of each other's responsibilities and constraints. Not only is this happening at the expert multidisciplinary level of PHARM, but the major organizations have also shown considerable commitment to making the council set up by the Minister work. This is a new model of health in this country.

"Dr Mary Merry ridge is chair of the Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee which advises the Minister for Health and the Department of Health about the upgradability of the system and encourages activity amongst community, health, professional, industry and government groups.

For further information write to: PHARM Secretariat, Pharmaceutical Benefits Branch, Department of Health, Housing, Local Government and Community Services, GPO Box 9860, Canberra ACT 2601, Australia."
UK GPs cautioned on new drug prescribing

"Patient awareness" is a new promotional tool being used by the pharmaceutical industry alongside its traditional methods of advertisements, direct mail, and visits from medical reps, the UK Medicines Resource Centre (MeReC) tells GPs.

Recently articles in newspapers, general interest magazines, and television programmes have preceded or accompanied new drug launches, the MeReC bulletin notes. They sometimes mention drug names and often draw attention to the alleged inadequacies of current therapy or the high incidence of the condition to be treated, creating the perception that something better is needed and is on the way, it adds.

Self-assessment symptom questionnaires have also appeared in GP waiting rooms as educational "services to medicine", sponsored by companies marketing a new product. They may never use the drug name but may show the company logo, colours, and typefaces used in promotional literature, the bulletin comments. The effect, MeReC suggests, may be to urge the identification of symptoms and encourage consultation with the doctor. Matching promotional material for the condition reminds the GP that there is a new product available.

Advice

The bulletin gives doctors advice on how to approach the prescribing of new drugs. They should ask whether the product really is a new chemical entity and a truly novel medicine, or whether it is a "me-too" product, or new formulation of an existing drug. They should also consider whether the licensed indications for a product define its appropriate place in therapy, MeReC recommends. It says that a licence for first-line use does not necessarily equate with its use as first choice.

Doctors are also advised to consider the efficacy of the drug for the intended condition and the quality of the evidence for its efficacy. MeReC comments that clinical trials need to be constructed to exclude bias in as many parameters as possible. As few trials are conducted in general practice, careful consideration of the patient groups, the drugs used for comparison, and the clinical environment is therefore needed in order to be able to interpret the therapeutic evidence and evaluate the drug's place in therapy, it suggests.

Discussing safety, the bulletin recommends that a benefit-risk assessment needs to be applied to every drug prescribed for every patient. Noting the relatively small numbers of patients who can be included in clinical trials (for many new drugs it will be between 1,000 and 3,000), MeReC declares that a product licence "does not and cannot provide a safety guarantee. Doctors who prescribe new products are taking part in an extended clinical trial and must be aware of, and prepared to accept, the extra vigilance that is needed."

"Innovative prescribers" are warned that they must report all (not just serious) ADRs to the CSM, using the yellow card system.

Reps' influence

While about 10% of UK GPs have "see no reps" policies, no single source of prescribing information exceeds the influence of the rep, the bulletin notes. In an average four-week period a GP sees about six reps but some see many more. Representatives should be thoroughly questioned on the data they present on new drugs so that the whole picture emerges, it advises.

MeReC advises doctors to read non-industry information, such as the Drug and Therapeutics Bulletin, and information bulletins prepared by drug information pharmacists in many NHS regions. It also suggests information sharing among practice partners, medical colleagues, local consultants, and community pharmacists.

Health economics

Referring to increasing use by companies of cost-benefit, cost-effectiveness arguments, the bulletin says that some responsibility must fall on non-industry bulletins to develop expertise in evaluating health economics arguments. One problem at present is that savings from reduced hospital stay, for example, are not immediately reaped by the GP who has prescribed a more expensive but overall more cost-effective medicine.

Recently, premium pricing of new medicines has been seen on an increasing scale, MeReC says. It argues that new products have not been priced to reflect profit and R&D spending but rather what the company thinks the customer (NHS) should pay.

MeReC is funded by the Department of Health. Its remit is to provide professional advice and information for all GPs in England on medicines and prescribing. Articles are written by MeReC staff (three pharmacists) and circulated to doctors and other experts for comments and to other medical and pharmaceutical advisers throughout England.
RATIONAL USE

The Commonwealth Pharmaceutical Association

Raymond Dickinson*

It seems to be a fairly popular misconception that the Commonwealth Pharmaceutical Association (CPA) represents pharmaceutical manufacturing companies. In fact, the main members of the Association are the national professional bodies for individual pharmacists, and also a personal member category as well.

Pharmacy is done with all aspects of medicine and medicine patients are employed within manufacturing companies in research, production, quality assurance and marketing, many others - particularly in the more developed countries - are engaged in the hospital service and primary health care, in the public and private sectors. These pharmacists are increasingly concerned with promoting, to health professionals and patients, the rational use of medicines.

Like its members, CPA is concerned with all aspects of medicines, and its overall objective is to ensure that those who are prescribed or who buy medicines receive the best possible therapeutic care. To achieve this aim CPA encourages the highest possible standards of pharmaceutical education, practice and professional conduct in all Commonwealth countries.

Of the 38 member associations, 30 are in less developed or developing countries (according to UN classification). This contrasts sharply with the other major international organization for pharmacists, the International Pharmaceutical Federation (FIP), in which most of the member associations are in developed countries. These differences are reflected in the emphasis given to the activities of both bodies. CPA is constantly striving to develop further the basic pharmaceutical service in the majority of its member countries, whereas FIP places equal emphasis on meeting the pharmaceutical needs of their member countries as well as developing countries. The two organizations complement one another and seek to cover most of the pharmaceutical world by collaborating whenever possible in international affairs. Both are officially recognised by the World Health Organization and work within that body as a team whenever possible.

The relative affluence of the member associations of the two bodies is reflected in their balance sheets. Remarkably, CPA functions on an annual income of about £5,000 which is made up of membership subscriptions and an annual grant from the Commonwealth Foundation, a body sponsored by Commonwealth governments, which promotes and sustains Commonwealth professional associations and non-governmental organizations (NGOs). There is, however, no funding from the Royal Pharmaceutical Society of Great Britain, which does not make any charge for the part-time activities of the Secretary of the Association (who is Deputy Secretary of the Society) and his support staff. Nevertheless, the funds are only sufficient to support the regular newsletter, occasional regional activity, the four yearly Council meetings (one member from each country) and the biennial meetings of the Executive Committee, and a number of projects.

So what can an organization with such limited resources achieve? The development of international policies and standards in relation to the objectives of the Association is not a costly exercise and has produced a considerable number of documents which are of great assistance to member associations in seeking to develop their profession and the services they provide. There are policies on pharmaceutical education, professional ethics, rural services, the principles of pharmaceutical legislation, expiry dates of medicinal products, and the benefits of dispensing by pharmacists. Other policies which will soon become published relate to the pharmacist's role in cost containment within

Top: CPA representatives visiting the pharmacy store at the Postgraduate Medical Hospital, Dhaka. Bottom: CPA representatives visiting a Dhaka pharmacy during their visit to Bangladesh.

Association and within its members, as well as a digest of international pharmaceutical developments.

CPA has established its "Pharmaid" scheme. The British National Formulary is published every six months by the British Medical Association and the Royal Pharmaceutical Society, and distributed to all doctors and pharmacists in Great Britain. This has meant that once a year, with the help of a national pharmaceutical wholesaler, it has been possible to collect the two previous issues which are no more than a year out of date. The books are dispatched by the Ranfurly Library Service to contacts in Commonwealth developing countries, to be collected by CPA members and distributed to pharmacy schools, pharmacists and health professionals. The cost of the scheme is minimal and for the last six years there has been an average annual distribution of 10,000 copies.

Pharmacy schools in developing countries need a wide range of reference sources. CPA helps by linking pharmaceutical manufacturing companies with schools so that recently outdated reference material from the company libraries can be redistributed. It has not been possible to include Indian pharmacy schools in this arrangement because there are so many, but through the Association's efforts, about 90 British pharmacists send at their own expense their weekly copies of the Pharmaceutical Journal to such schools.

More recently CPA has initiated projects to develop distance training packages for the benefit of pharmacy schools, continuing education programmes and particularly for those who practice in isolated locations. With funding support from the Commonwealth Health Development Programme, West African pharmacy schools are being provided with a package on communication skills, to be launched with a "train the trainers" course by the authors who come from Northern Ireland. This will assist pharmacists to develop their advisory roles. Work has also commenced with the Commonwealth of Learning on a project to develop a self-study package on the management of drug supplies, with a tutor-assisted learning option, in collaboration with WHO's Action Programme on Essential Drugs.

An overriding aim of CPA is to persuade national governments of the benefits that they can enjoy from the proper use of pharmacists, at all levels and in all activities related to medicines.

In addition to their more commonly recognized roles in community and hospital pharmacy as members of the health care team, pharmacists have an important role to play in regulatory control and drug management, manufacture, information to health professionals and the public, quality control, research and training.

As a follow-up to the 1990 WHO Consulation on the Role of the Pharmacist in the Health Care System, CPA is collaborating with FIP and WHO to prepare a report intended to demonstrate how material benefits can be gained by the proper use of pharmacists in health care systems.

The Commonwealth Pharmaceutical Association may be relatively small in terms of the number of member associations, active workers and funding, but it is committed to targeting these resources to projects that will be of practical and lasting benefit not only to its members but also to patients throughout the Commonwealth who can benefit from pharmaceutical services of satisfactory standard.

* Raymond Dickinson is Secretary of the Commonwealth Pharmaceutical Association, 1 Lanesbith High Street, London SE1 7DN, UK.
RATIONAL USE

Rational drug prescribing in the United Kingdom:
an interview with Professor J.C. Petrie

EDM: When did you first hear of the concept of essential drugs?

JCP: It was in the seventies when it was first announced. I believe the first WHO model list of essential drugs was published in 1977. Initially I was quite upset about this list because, like most people, I initially misunderstood its objectives. But as I came more and more to realise that this was a "model" list, to be modified to meet different needs and circumstances, I began to be very sympathetic to the concept and aims.

EDM: Do you believe that the essential drugs concept has an application in developed countries such as the United Kingdom?

JCP: Yes, certainly. We have found that it is extremely helpful in several ways. For example in teaching about rational therapy it is very useful to our undergraduate students and clinicians as it identifies a "core" of information about drugs prescribed. The concept is also invaluable in helping to contain the costs of drugs and without impairing the quality of care. As you know, hospital drug budgets in the United Kingdom are cash-limited, and if money is not used appropriately, other aspects of the service may suffer. This might include a restricted availability of hospital beds, support staff or other facilities. Hospital doctors and nurses in the United Kingdom have therefore to be increasingly rational in their choice of drugs. I am pleased to say that in some centres such as ours we have managed to limit the purchase and supply of drugs within hospitals to a limited list through voluntary agreed policies, which are arrived at by widespread consultation. We consult extensively with primary care physicians and hospital specialists and our lists are determined only after considerable discussion. The result is that we categorise our recommendations for the selection and purchase of new drugs according to the desirability of either widespread availability throughout the hospital or of limited availability for selected indications according to defined guidelines, which are closely monitored. In the latter group we would include drugs such as ondansetron and cimetidine, which have recently been introduced and which, because they are so expensive, could potentially have a huge impact on drug budgets and lead to unpredicted overspends. However we are quite clear that our principal aim, which is shared by the specialists and primary care practitioners whom we consult, is to use the essential drugs concept in terms of formulary development primarily to improve rational prescribing rather than to curtail costs. We do not believe that we can convince funding authorities to pay for new drugs unless the clear therapeutic advantages of such new products are demonstrated and unless we can prove that we are already using established drugs in a rational and cost-effective manner. To continue to prescribe unnecessarily and at excessive or unnecessary cost does not help an argument that there is under-funding for established and new drugs.

EDM: This is also a relevant argument for developing countries.

JCP: Yes, I think that in principle the situations are very similar. I believe that the rational prescribing of drugs and the value of limited lists applies equally to the UK and to developing countries.

EDM: As a medical student, how were you taught to prescribe? Was it a sort of cookbook medicine: "If you see this disease, that is the medicine you give?"

JCP: As undergraduates we did not have a focus on teaching in clinical pharmacology. In the early sixties we were exposed to biochemistry as a subject and to physiology, whereas in those days pharmacology had not clearly emerged as a separate discipline, far less clinical pharmacology. Just before my time medical students and young doctors were still trained in laboratories to compose mixtures together. My professor of Materia Medica had just shown that thyroid extract was an ineffective substance - a forerunner of a biosafety study! We were introduced only to clinical medicine, not to global subjects such as antipsychotics, which was the use of medicines. The principles of clinical pharmacology really evolved in the early 1960s around the time of the thalidomide disaster. This made the public aware of the professionals that we had to become much more aware of the mode of action of drugs, the adverse reactions and their kinetic and dynamic influences and interactions.

EDM: Now, as a professor of clinical pharmacology, you have much influence both on prescribing and on the teaching of therapeutics. Can you summarise your main philosophy?

JCP: I believe that we should try to define the core of the subject, that is to say the principles underlying the rational use of drugs. I think it is important that a glossary of keywords become familiar to the prescriber, and that he or she understands the concept of the indications for a drug, its mode of action, the kinetics and the dynamics and interactions as they apply to their use in diseased patients. We believe in limiting the range of drugs to which the students are exposed in order to keep the information clinically relevant and fairly simple. Also, more recently, we have been trying to focus on developing teaching and learning objectives, so that we do not overload students with information that they will not require in their prescribing lives. It is far more important to get a firm grasp of the principles underlying rational prescribing rather than being overwhelmed with information about the very latest drug. So we have evolved towards the concept of limited lists and formularies in the United Kingdom and in our medical school. This is very helpful to students in developing a practical database and also in appreciating the principles underlying the choice of drugs for developing personal formularies.

EDM: What advice would you give to medical schools and medical students in developing countries?

JCP: I would encourage them very much to adopt the same principles in terms of selecting their own core lists of drugs. I would counsel them most strongly against taking the advice of the latest information from vested interests or market forces, who have as their primary motive a profit for their shareholders rather than benefits for the community as a whole. If one does use new products one has to recognise that, within limited resources, another aspect of the health care service, or the community, may have to suffer. Until clear advantages emerge for a new drug through rigorous clinical trials, I see no justification for purchasing and prescribing. Certainly that is the philosophy that we adopt in our formulary development. We oppose the introduction of new drugs in our formulary list because of their novelty and the benefits of rigorous clinical trials have shown them to be better for the patient and cost-effective for the system as a whole.

EDM: In many countries there is, besides a government health service, a private health service with private practitioners and pharmacies. What do you consider the best way to promote rational prescribing among them?

JCP: In the United Kingdom drugs are available if they have been approved by regulatory authorities. For example, if one looks at the British formulary, for antibiotics, we do not permit their sale without prescription over the counter at pharmacies. Where such policies do not apply, their overuse is undoubtedly leading to a fairly major public health problem in some countries in the sense of the emergence of resistant bacteria. It also has the consequence that increasingly expensive drugs have to be used as resistance until a cheaper drug emerges. I think that the key element is to teach our young doctors - whether they will go into private practice or public service - the principles of rational pharmacotherapy. They need to know how to evaluate and monitor drug therapy, and what are the objective sources of information about drugs. Above all, we need to hammer home the understanding that "more expensive" does not necessarily mean "better". Excellent drugs are often very cheap. A drug can be considered essential if it is of proven efficacy in specific circumstances by carefully controlled studies.

J.C. Petrie is Professor of Clinical Pharmacology at the University of Aberdeen in Scotland. He serves on the UK Committee on the Safety of Medicines and its subcommittee on pharmacovigilance. He is also President of the Audit and Research Unit of the Royal College of Physicians of Edinburgh, Scotland.
The drug information cascade: making it more effective in daily practice

Andrew Herxheimer*

On 5 March the Northern Ireland Faculty of the Royal College of General Practitioners launched the third edition of its Practice Formulary, the fruit of long collaborative work by GPs, medical specialists, pharmacists and clinical pharmacologists. The example of this interdisciplinary collaboration prompts some reflections about how we can make formularies, drug bulletins and drug information centres work together more effectively.

A selective formulary, like the Practice Formulary, is an everyday guide that can help doctors to choose and use the most appropriate medicines for common problems. But it is more: it can facilitate communication and mutual understanding between doctors, nurses and patients, for it proposes a shared therapeutic agenda and priorities within that agenda. To make such selective formularies as effective and as useful as they can be, we need to examine how they fit into the larger picture of information flows about medicines.

Information sources: the whole truth?

We are all only too familiar with the flood of promotional information that doctors, pharmacists, and increasingly also the public, receive about medicines. This information quite legitimately seeks to make us aware that particular products exist and can be prescribed, but the claims made in it are intended to promote their use and not impartial evaluation. One could reasonably describe pharmaceutical promotion as the truth, the half truth, and nothing like the truth.

Independent information reaches us from a variety of different professional sources - international, national, regional and local. Some of these overlap.

International sources include major medical journals, such as the Lancet, the British Medical Journal, the New England Journal of Medicine, and the World Health Organization, but all these have relatively little direct influence on prescribers. Their importance lies more in their influence on other professional information providers.

At a national level, national formularies are supplemented by therapeutic guides and prescribers’ bulletins, such as Drug and Therapeutics Bulletin and The Medical Letter. Each has a specialised core staff with easy access to a network of nationally eminent and experienced advisors. Then there are product data sheets which give the manufacturers’ product information accepted as valid by the national drug licensing authority - but unfortunately much of this is presented in a style that is legalistic and difficult to use. Regionally there may be selective formularies, like the Practice Formulary, together with regional bulletins and newsletters. These can be important links within a region, fostering convergence and sometimes even therapeutic harmony among colleagues, and reducing confusion among patients.

Locally the picture is less formal and much more variable: there may be hospital or district formularies, and general practice formularies, treatment guidelines for hospital staff, and guidelines or policies or protocols for shared care between hospital and general practice. These printed documents are supplemented by letters and conversations between hospital doctors and GPs about individual patients, and between pharmacists in drug information centres and local doctors and pharmacists about particular problems.

We can regard the whole picture as a cascade in which information runs in two dimensions. One dimension runs from the general - which applies to all or almost all patients with a certain problem or using a certain drug - to the particular, the individual patient in whom various special aspects have to be considered. The other dimension links medical science, which is rigorous and international, to medical practice which is much more pragmatic than scientific, and reflects local traditions and culture, and individual doctors’ training, experience and personality.

I believe that a smoothly functioning and efficient information cascade is an essential part of a satisfactory health service. There are many ways in which we need to improve the cascade in the future.

Using information wisely

First, at the input end of the cascade we must make it easier to separate valid from scientifically dubious information. Independent drug bulletins were started with this aim and have achieved considerable success. But they have so far not benefited from the general body of biomedical literature, nor can they tackle the problem comprehensively or in depth. It requires efforts at a much larger scale, to encourage and assist systematic, critical reviews of the results of randomised clinical trials, and disseminate these reviews.

Second, within the cascade, we need closer and better collaboration at and between the national, regional and local levels. We must recognise that the provision of good, user-friendly information is an interdisciplinary activity, and requires contributions from clinicians of various kinds, clinical pharmacologists and pharmacists.

Third, we should stop behaving as if the work of drug information centres, the creation of formularies and the production of bulletins were separate activities. They complement one another, and each benefits from close working links with the other two. We should make a real effort to involve the same people in all three kinds of work.

Fourth, we must try to bring the information that prescribers need so close to their everyday work with patients that they can bump into it without having to remember to look for it. The development of therapeutic guidelines which can be linked with the formulary information is an important step in this direction. And of course as we get better at integrating the necessary information into everyday practice, we shall also be better able to audit what we do and to improve it. There is much dramatic work at a primitive stage. It needs to be accepted and practised as a normal part of clinical work.

Raising public awareness

Last, the information cascade will have to be extended to the public, the users and potential users of health services. Moves in this direction have begun. In the UK, which has been very backward in this area, there will finally be information leaflets with all medicines in the next few years. And various books for the public on medicines have been published. But nothing has yet been done to teach or train doctors in how to explain medicines and other treatments to their patients, and how to discuss with them the choices to be made. They either gradually learn these skills, or more often they don’t and remain unaware that they explain too little and too obiously. Patients can contribute by asking specific important questions about their medicines, and a short list of such questions could usefully be distributed by general practices and pharmacies.

Nor has anything been done to educate the public about the basic concepts that users of medicines need to understand. Examples are the relation of dose to efficacy, the effect of different drugs on different patients, the duration of actions of different drugs, and the differences in the way that different patients deal with the same drug.

Clearly a great deal of work still has to be done to improve our use in practice of the relevant knowledge about drugs. Every explosion of knowledge is accompanied by a corresponding explosion of ignorance, and we must do our best to upgrade the information cascade so that it can cope smoothly and efficiently, not only with our present needs but their future expansion. Wholehearted contributions from pharmacists, clinicians, clinical pharmacologists, nurses and others are essential, and it is surely time for each country to work out a national agenda for getting on with the job.

* Dr Andrew Herxheimer is a consultant at the Cochrane Centre, National Health Service Research and Development Programme, Oxford, United Kingdom. He is also Chairman of the International Society of Drug Bulletins.

Based on a talk given at the launch of the 3rd edition of the Northern Ireland General Practice Formulary. A modified version of this article first appeared in Pharmacy Journal, 27 March 1993.
Essential Drugs Monitor


Almost half the people living in cities in developing countries exist in conditions of extreme poverty and insecurity. This report alerts us to an impending health crisis as urban populations continue to grow. Traditional health problems, chronic diseases, and injuries caused by violence and road accidents are all increasing. We also have to deal with the problems of HIV infection and AIDS, alcohol and drug abuse.

While noting the general shortage of resources for urban health, particularly in poorer areas, the report calls for even greater organizational and administrative changes which could help health administrations and municipal authorities overcome their problems. It shows how to analyse the weaknesses in urban health systems, assess options for strengthening primary health care, and that reproductive health care, which help the population to be taken care of, both for short-term and long-term changes that have brought improvements.

The report introduces the concept of "reference health centres", which could provide an extended range of both qualitative and quantitative health services in defined catchment areas and link with hospitals for referral support. The aim is to make health services accessible to all city-dwellers on a more equitable basis, with an urban health centre supporting and strengthening the primary local health care centres.


Almost 100 countries worldwide are still affected by cholera, and experience has shown that its introduction into a country is impossible to prevent. Unchecked, an outbreak of the disease rapidly reaches epidemic proportions and may result in many deaths. However, improved methods of surveillance, diagnosis and treatment, coupled with better standards of sanitation and personal hygiene, can significantly limit the spread of infection and minimize the public health problem.

These practical guidelines are based not only on intensive research and experience with the disease and the most effective measures for its management. Throughout, emphasis is placed on the importance of safe water, scruptulous personal hygiene, and careful food preparation as the most effective preventive measures. Readers are also alerted to public health interventions, such as vaccination, which are ineffective or wasteful and therefore to be discouraged.

Other issues covered include what the authors view as the comparatively poor official information on pharmaceutical products in Peru; the use of subliminal images in advertisements; and the use of prizes as incentives to persuade doctors and pharmacists to use particular products.

This analysis of pharmaceutical advertising concludes that there is much to be done to improve the often misleading, inadequate information provided by drug companies, aiming to increase their share of the market.

Essential Drugs Monitor

PUBLISHED LATELY


The economic, business and industrially oriented aspects of the pharmaceutical industry, rather than medical issues, are examined in this publication, whose authors are specialists in industrial research at the UN Industrial Development Organization. It includes information on production and consumption, trends in international markets, and the role of research and development, with many informative tables supplementing the text.


What has happened in developing countries, since worldwide pressures have forced multinational drug companies to begin correcting, what the authors describe as, “their notorious abuses”? On the basis of detailed research, the authors conclude that in many cases small, local firms have adopted the same dishonest sales strategies as the multinationals which they replaced.

The book claims that these local drug firms have taken advantage of loose regulatory practices, and uncritical behavior on the part of health care professionals, in order to sell dangerous or worthless drugs as remedies for diseases for which they were never intended.

Norplant Under Her Skin, B. Mints, A. Hardon and J. Hanbury (eds), 1993, 126 p.

This first book on women’s experiences with the new contraceptive Norplant describes how Norplant has been used in Indonesia, Thailand, Egypt, Finland and Brazil, and includes an overview of acceptability studies of the contraceptive. It was produced by the Women and Pharmaceuticals Project (Women’s Health Action Foundation), a Dutch-based NGO active in women’s health and development. The authors assess the impact of this contraceptive on women’s well-being. They describe examples of infringements of human rights and disregard for safety in the way that Norplant is provided, particularly in Third World countries.

Norplant: Under Her Skin

Norplant is a hormonal contraceptive consisting of six rods which are implanted under the skin of a woman’s arm and gradually release a synthetic form of the hormone progesterone. It is effective for five years and must be surgically inserted and removed. Norplant is 99% effective.

The contraceptive, developed by the US-based Population Council, is currently registered in 26 countries and used by approximately 2.5 million women, most of whom live in Third World countries. As a highly effective long-term method which does not require daily attention, it is heavily promoted in some family planning programmes.

The design of this contraceptive, says the report, makes it prone to abuse because of the need for surgical removal. High costs for medically safe use also make it inappropriate for many Third World family planning programmes, the authors add. The Women and Pharmaceuticals Project strongly recommends that, “If Norplant cannot be provided safely and respectfully, and with a woman’s fully informed consent, it should not be provided. It is not enough to say that certain conditions must be met, but to turn a blind eye when they are not met (…) Policy makers, donor agencies and non-governmental agencies (NGOs) involved in contraceptive development have a role to play in ensuring that the needs and well-being of contraceptive users come first.”

Available from: Women’s Health Action Foundation, PO Box 4263, 109 AG Amsterdam, The Netherlands, Price: NLG 22.50


A seminar-workshop, held in Manila in February 1992, gave medical journalists an opportunity to enter into debate with policy makers and experts in the field of health and pharmaceutical policies. The seminar was based on the premise that the media are the key to informing the public on basic issues, such as how pharmaceutical companies sell drugs, the worth of their medicines, and the ways by which they are prescribed.

This book reports on the proceedings of the seminar, which was attended by experts from around the world and was organized by the Philippine Centre for Investigative Journalism and the Dag Hammarskjold Foundation. It includes extracts from speeches delivered in Manila which recount the growth of national drug policies, the concept of rational drug use, and the experiences of different developing countries as they have tried to implement them. The journalists present drew up a list of the common, basic points to be addressed by all reporters covering the health sector. Prescription for Change concludes with a “sourcebook” of information on national and international health agencies devoted to health issues and social change, which provide an invaluable resource for the media.

Available from: Edward Elgar Publishing Ltd, Gower House, Crock Road, Aldershot, Hants, GU11 3HR, United Kingdom.


The modern term “community financing”, is often used to define a vague concept. Most users understand community financing to mean financial resources come neither from the state nor from external sources. In the context of the politics of structural adjustment, community financing is a way of compensating for a government disengaging itself from providing a state funded health service.

Many African countries are now following the same route. The results of some experiments there have been among several years, and whilst they arouse interest and hope, equally they raise a lot of questions about the idea of community financing, its philosophy, its efficacy and attendant risks.

This review reports on a workshop held in Paris in September 1991, jointly sponsored by the Action Programme on Essential Drugs, the Centre International de l’Enfance, UNICEF, and the French Cooperation Ministry. The focus is on one key question: how to arrive at a fair and viable means of financing health services and medical supplies in Africa?

The publication examines the roles of the state and the community in financing a health service; how to reconcile equity and efficacy in the African context; and the consequences these new financing strategies may have on the supply of medicines and the policies of essential drugs. It also highlights the technical and financial question of what global financial strategies should be promoted in developing countries?

Available in French only from: CIE, Chaussée de Longchamp, Boîte de Boulogne, 75010 Paris, France.

Important

The Action Programme will supply the publications reviewed on those pages. Please write to the address given at each item.


Written for medical students undergoing clinical training in paediatrics, this manual aims to provide them with the necessary knowledge to assess patients, plan treatment, and prevent deaths through proper case management. The information is specific to conditions in developing countries and is divided into eight teaching units. Topics include pathophysiology, epidemiology, causative agents, methods of transmission, dehydration, dysentery and diarrhoea associated with other illnesses.

The book stresses the importance of prevention, and focuses on methods of educating families, particularly mothers, on their role in preventing diarrhoeal disease.


This interesting study examines different aspects of the Bolivian Health System, both failures and successes. It looks at the irrational use of modern drugs and the failure to provide integrated and comprehensive health care. Many Bolivians have little or no access to modern medical technology, it reports, and rely instead on traditional medical practices, values and beliefs, which enjoy considerable social confidence. Despite his orthodox medical background, the author defends popular knowledge about the health-disease process which, he says, is frequently disregarded by health decision makers.

Available from: AIS Bolivia, Caudía Potosí, 585, La Paz, Bolivia.


Vaccine Supply

The first line of defence

Throughout the world, millions of children are immunized each year. Immunization is perhaps the most effective and efficient way of ensuring the health of the world’s children, as it acts before the risk of disease arises. Since 1977, an increasing percentage of children have received vaccines against polio, measles, diphtheria, whooping cough, tetanus, and tuberculosis. The declining incidence of these diseases reflects the impact of immunization. Reported cases of polio, for example, decreased from about 60,000 in 1982 to just over 13,000 ten years later. New and improved vaccines are being developed to provide even greater health benefits. However, success has brought a different kind of problem.

Now a crisis in funding for vaccine supply has arisen. This situation is complicated by donor fatigue, rising prices, increased need for vaccines for new disease control initiatives, and the promise of new, though more expensive, products.

In order to tackle the problem the Children’s Vaccine Initiative (CVI) was launched in 1990. This coalition of public and private organizations is dedicated to supplying children’s vaccines which provide lasting protection against a wide range of diseases. It favours vaccines that are simple to use and inexpensive. It recognizes that although it is highly desirable to provide new vaccines, this cannot be done until problems in vaccine supply are overcome. A Task Force has, therefore been set up which will concentrate on strengthening supply systems.

Vaccine supply strategies

No single supply strategy is right for every country. The most effective strategy depends on many factors, such as the size of the country, the type of infrastructure development, and the vaccine in question. There are three possible supply strategies: procuring vaccine, production sharing, and production. Production sharing means importing one or more components of a vaccine and then blending, filling and/or packaging locally. This strategy is likely to become more important as it enables countries to use local resources and industries, and makes quality control easier.

To gain a global perspective of the current supply systems, a preliminary analysis was made by plotting on a grid the wealth and population size of 130 countries (see figure 1). Each square represents a country. Filled squares indicate countries which already produce vaccines. Production is economic when the manufacturer can spread the manufacturing costs and quality control across substantial quantities. So production may be economic for countries with a large guaranteed market. Whereas for middle-sized and smaller countries, procurement is more economic. Local preparation of vaccine to meet domestic needs should not, therefore, be the target for very many countries.

The high income countries at the top of the grid, containing 9% of the world’s children, do not require aid to meet their own vaccine needs. These countries also provide vaccine to developing countries, and are responsible for much of the research and development work that is done.

The lower income countries at the bottom of the grid need the most support. This can be achieved by helping:

- Smaller countries to procure vaccines;
- Medium sized countries to procure and/or share in production (depending on their relative wealth and size and the availability of vaccine production facilities);
- Larger countries to procure and/or produce their own vaccines.

This framework has helped to identify countries for priority action. Fourteen countries on the right of the grid, including China, India, Egypt and South Africa, will be visited by teams of experts in vaccine production, quality control, demand forecasting, and economics. These visits will lead to the development of vaccines and plans designed to facilitate the production of high quality vaccines in sufficient quantities.

The need for procured vaccine will also be assessed. Twenty other countries have been identified as priorities for improving procurement strategies, in collaboration with donor agencies and UN organizations.

Funding

For some developing countries involved in procuring vaccines, the introduction of revolving funds has already enabled them to finance their own vaccine needs. Many countries in Latin America procure some or all of their supplies through the Pan American Health Organization Revolving Fund, which has been working well for 14 years (see figure 2). The UNICEF Vaccine Independence Initiative is now being offered to all countries and is also based on a revolving fund. The purpose of the initiative is to provide countries with services to assure a sustainable supply of high quality, affordable vaccines.

For some countries, however, the world recession has caused a reduction in funding for vaccines from donor nations. Yet the economic benefits of disease eradication, through immunization programmes, far exceed the cost. The global initiative against polio illustrates this. Savings in the cost of treatment and rehabilitation mean that if the present progress is maintained, the initiative could pay for itself by the year 1998, and produce savings of half a billion dollars by the year 2000, increasing to US$3 billion by 2015.

Forecasts

Increasing the accuracy of forecasting will help planners assure an adequate supply of the vaccine and the necessary budget to pay for it. New strategies aimed at achieving disease reduction and elimination, together with higher immunization coverage targets and the introduction of new vaccines, all make forecasting the demand for vaccines more complex, however. The Task Force found demand forecasting to be very weak in most countries and one of its priorities is to provide new training materials on how to improve accuracy in this area. Linked to this, the Task Force is also working with countries to study their current levels and causes of vaccine wastage.

Vaccine wastage is a major problem for those trying to estimate future need for vaccine. During the 1980s, access are accepted as a necessary cost if vaccination programmes are to reach the maximum number of children in a country.

Looking ahead

The demand for vaccines today is five times greater than ten years ago. This figure is likely to increase with new strategies to reduce and eradicate disease and increase immunization coverage. To reap the benefit from the new and improved vaccines currently being developed, it is essential to ensure adequate funding and efficient, reliable supply systems.

Work needed on vaccine coverage even in developed countries

In a recent speech President Clinton pointed out that the overall need of a full series of immunizations has only grown by approximately 23% a decade ago to more than US$25 billion today. Currently, only 40-60% of pre-school children in America receive the recommended vaccinations, a figure which drops to 10% in some areas in the country. To meet this daunting situation, the Clinton administration is considering a plan for the government to purchase all the childhood vaccines used in the US, and distribute them free to both public and private clinics. US vaccine manufacturers say the policy would eliminate competition, and even companies that cut research programs, while the government argues that by controlling the market and stalling prices it can give a much-needed boost to the country’s immunization programme.