Essential Drugs Monitor

Nº 22 (1996)

Essential Drugs Monitor

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

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

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In this issue:

Winds of change

EDITORIAL

The winds of change are blowing throughout the pharmaceutical sector: in national drug policy; in global trade; in drug regulation; and in approaches to evidence-based drug information. This EDM highlights some of the benefits, uncertainties and risks of a changing scenario.

Countries are reviewing sometimes long established national drug policies to evaluate their functionality and relevance in the new environment. They face the challenge of retaining the focus on equity and public interest that must underlie any health policy, while building on experience and new opportunities. The report from Iran, in this issue, exemplifies one such process. In some countries the winds of change have at times been more like hurricanes. In Central and Eastern Europe and the New Independent States, countries are facing acute problems. In the pharmaceutical sector hasty privatisation, combined with lack of proper control and regulation has created a paradoxical situation in which drug availability has improved but affordability has decreased.

In global trade the pharmaceutical sector is also evolving; and in ways which many developing countries fear may not be to their advantage. Multinational companies are merging, and in the process concentrating important elements of market share and product lines into fewer hands. Harmonisation of registration requirements for new drugs has been confined to drug regulatory authorities and research-based manufacturers in Europe, Japan and the United States. But perhaps the major change will derive from the GATT Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). This grants member countries a minimum of 20 years' patent protection. The impact on developing countries cannot yet be known. However, a recent study, being published jointly with the WHO Task Force on Health Economics, concludes that, although patent protection will be enhanced, this will not necessarily be to the benefit of all countries. Concern is raised about the potential impact of new trade arrangements on health and, in particular, on access to essential drugs. When incorporating the Agreement into domestic legislation, countries will need to decide when and how to draw on its exclusion provisions. These provisions include the right to grant compulsory licences under certain conditions, such as to protect public health and interest.

Drug legislation can be expected to change in other ways. Voices from many quarters are calling on drug regulatory authorities to change working practices and priorities. In the letters page, a UK pharmacologist argues that regulators expend more energy on licensing new products than on reviewing the effectiveness, safety and use of marketed medicines. Product licence renewals are often a bureaucratic formality without any scientific review, and regulators have little day-to-day contact with prescribers and almost none with consumers. Reform is needed, he asserts. In the same section two pharmacologists from India call for more stringent control of marketed traditional medicines. And an international working group on transparency and accountability in drug regulation is advocating greater openness in how drug regulators handle drug quality and safety data, and monitor the use of medicines. Full availability of information is essential if all parties involved in health care are to participate effectively, the group concludes.

Although information underlying drug regulatory decisions is still inexplicably difficult to obtain in many countries, prescribing information is making rapid strides in some parts of the world. In Scotland and the United States, for example, professional associations are fine-tuning evidence-based treatment guidelines. Their approach describes the ***level*** of clinical evidence on which recommendations are based, providing users with a critical tool for optimal therapeutic decision-making and health service management. This work reflects the evidence-based selection process at the core of the essential drugs concept, demonstrating its universal applicability. In an era of increasing concern for both quality of health care and cost containment, no country in the world can afford to disregard such careful assessment of therapeutic benefit and related costs. When clinical options are fully reviewed, compared and prioritised, this can free up resources to provide wider and more equitable access to effective treatment, including the small, but important number of true innovations in pharmacotherapy which become available each year. ❑

NEWSDESK

Australian consumers want more information

MANY of the projects sponsored by Australia's Pharmaceutical Education Programme have revealed that consumers want to know much more about their medicines than their doctor, pharmacist or nurse can tell them in a short space of time. As a result the Consumer Task Force of the Pharmaceutical Health and Rational Use of Medicines (PHARM) Committee is reviewing existing and previous health information services, reports *HAI News*, August 1996. PHARM is keen to facilitate the development of sources of accurate information, which will be easily accessible by all consumers, wherever they live and whatever their circumstances. Currently some information sources are limited to particular states, but there have been discussions about establishing a national telephone service to enhance the appropriate use of medicines. ❑

Specialised public sector drug management training in Africa

PHARMACISTS, economists and health administrators from nine African countries (Central African Republic, Congo, Guinea, Madagascar, Mali, Mauritania, Niger, Sao-Tome & Principe and Senegal) attended this first specialised training course on drug management for the public sector in Africa. Held in Dakar, Senegal, from 15 April to 7 July 1996, the course was organized by the University of Montpellier, with DAP financial support, and with fellowships from various sponsors. Lecturers included medical, academic and senior pharmaceutical management staff from Côte d'Ivoire and Senegal, hospital, university and industry staff from France, and DAP staff.

Theoretical and practical training focused on drug management, selection criteria, quantification of needs, national drug policy issues, generic drugs and informatics. Case studies from such countries as Côte d'Ivoire and Senegal stimulated practical problem-solving skills. A second course is planned in Cotonou, Benin, for 1997. ❑

Drug promotion: Sri Lanka's new ethical criteria

IN January 1996 the Sri Lanka Medical Association adopted Ethical Criteria for the Promotion of Drugs and Devices in Sri Lanka. Formulated by the Association's Ethics Committee (composed of GPs, academics, clinical pharmacologists, family practitioners and medical administrators), the Criteria are closely based on WHO's Ethical Criteria for Medicinal Drug Promotion. However, they have been expanded to cover medical devices and dental and veterinary practice. The Sri Lankan Criteria also specify that prices must be included in advertisements for both over-the-counter and prescription medicines.

The process of drawing up the Criteria was begun in 1993 and was finalised after wide ranging consultations and review of local legislation. Although not legally binding, the Association hopes that the Criteria will be adhered to by all involved – the pharmaceutical industry, its medical representatives and prescribers. The Criteria could also form the basis of future legislation. Current legislation on drug advertising is based on what should not be done; legislation based on the Criteria should provide guidance on what should be done, which would be easier, and would also encourage ethical activities, the Sri Lanka Medical Association asserts. ❑

British National Formulary goes on line

Anne Prasad, Dinesh Mehta*

COMPUTERS are increasingly being used by health care workers, hence there is a growing demand for electronic reference sources. It became clear that an electronic version of the *British National Formulary* (BNF) would be a valuable complement to the pocket book. By giving appropriate information at the moment of prescribing and dispensing, an electronic version could improve drug safety and could provide additional features to the book.

The aim was to take the *BNF* in its entirety to the computer screen and to maintain the same editorial handling of the data. Users of the pocket book version would see on screen the tried and tested format with which they had long been familiar.

The establishment of a database able to generate both the pocket book and electronic versions of the *BNF* was a complex exercise, which was planned in successive phases. The first phase would establish a simple relational database from which it would be possible to produce both typesetting files for the book and an electronic version suitable for distribution on disk or CD-ROM. In a second phase the electronic version would be developed so that it could be integrated with other clinical software, such as patient management systems.

Phase I development: focus on security

The *BNF* was already typeset electronically but the existing typesetting file had to be stripped of its formatting codes and broken down, in order to meet the more rigorous logic required for the purposes of a database. The typesetting codes were replaced and the resultant italics, bolds, capitals, and paragraph and word breaks were all rechecked. Nearly a quarter of a million words were moved from the typesetting file to the database and new checking procedures were developed to control this. Security was a key issue and involved many hours of additional proof reading. It was vital to ensure that no words were lost or jumbled during the transfer. A further complication was that routine updating for the next edition could not be abandoned during the transfer period.

BNF No.28 was the first pocket book version of the *BNF* to be published entirely from the new database. This was a crucial step, but there were further hurdles before the presentation had reached the standard required for display on a computer screen. Another year passed before the electronic version was ready. Finally, with the launch of *eBNF No.30* in November 1995, the first phase of development was completed. An electronic version of the *BNF* was at last a reality.

Phase I product: faster data retrieval

On screen the *eBNF* text is viewed in "column" form, as in the book. The programme allows the user to browse the data using various search commands, and additional electronic search facilities enable the user to retrieve information more rapidly from the electronic version. The data can be accessed by jumping directly into chapters, sections, drug monographs and preparations at will. An important feature is the ability to view information on a drug together with the interactions information appropriate to that drug. Other features allow the text to be enlarged on screen or for it to be printed out. Multiple hypertext links help the reader navigate through the many cross-references in the *BNF*, and user-defined annotations and bookmarks can be added.

Phase II development: linking to patient records

Development of the phase II version, now underway, involves detailed structuring of the information to allow the database to operate as part of an intelligent decision support tool. The aim is that the *eBNF* should be able to provide really valuable links to electronically held patient records. The *BNF* advice will continue to appear in its familiar format, but details relating to individual drugs will be associated with standard electronic codes, able to be associated with similar codes in an individual patient's record. The user will thereby be provided with highlighted advice relevant to an individual patient's condition. This requires a sophisticated interface between the *eBNF* and patient management systems. In recognition of the complexity of this task a stepwise development is planned, so that the *eBNF* can evolve in harmony with external developments in electronic prescribing and dispensing.

Phase II product: prescribing and dispensing support

The major feature of the phase II version of the *eBNF* will be the ability to retrieve and assemble information tailored to help with individual prescribing and dispensing decisions. The *eBNF* will thus join other similar applications to produce decision support systems. Another application of the phase II version will be its incorporation within a range of electronic books. The aim is that the user should be able to move easily from the *eBNF* into other electronic sources, such as clinical textbooks and drug bulletins.

The phase II version will also be able to act as a host to more detailed outside documents referred to in *BNF* guidelines. It will be valuable for the user to have background reference sources available at the press of a key.

The detailed structuring of information in phase II will allow manipulation of the data. For example, programming routines could permit the creation of comparative price charts which could be printed out for study and discussion.

Another important application will be to provide support for more specialised formularies. Initially, this will be relevant in the UK where major hospitals are increasingly developing formularies for their specific needs. Soon, the *eBNF* may also be able to provide similar support for formularies overseas. As electronic information increases and technology develops, there will be further phases to provide health care professionals with their information needs.

It is expected that these developments will assist in the evolution of prescribing and dispensing support, not only in the UK, but also in parts of the world where resources are more limited. ❑

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NEWSDESK

International campaign against secrecy in drug regulation

HAI-Europe and the Dag Hammarskjöld Foundation have published an international statement on the need for transparency and accountability in drug regulation. The statement was drawn up by an international working group of drug policy experts brought together by the two organizations.

The Statement of the International Working Group on Transparency and Accountability in Drug Regulation calls for greater openness in the way national and international drug regulators handle data regarding drug quality and safety, and how they monitor the public's use of medicines. Too often, it says, secrecy surrounds government decisions on drugs, which undermines public confidence in the regulatory process. Today, drug agencies often maintain secrecy to a much greater extent than law or logic actually demand, the statement continues. In principle members of the international working group believe that openness should be the rule and secrecy the exception.

The group argues that excessive secrecy slows the development of scientific knowledge, that it can be used to cover falsification or suppression of crucial data on drugs awaiting approval, and allows companies to withhold information on "unfavourable" research results. It can also lead to public mistrust when only partial information is released or regulatory decisions are announced without any explanation of the underlying reasons for them.

The statement says that two main arguments originally underlay the principle of regulatory secrecy in the drug field:

- First, it was considered that a commercial company which had used creativity and funding to devise and develop a drug could only reap a proper reward and fund future research by protecting it from immediate imitation by others. While patent law would protect certain matters, others could be protected only by maintaining secrecy.
- Second, it was realised that information relating to individual persons (for example, those participating in a drug research project or those in whom adverse reactions had been reported by physicians) would have to be dealt with having full regard for personal integrity.

These principles need not be questioned, the group argues, but they need to be more fully defined. On which matters does the need for secrecy really outweigh the general need for openness? Where is the dividing line between legitimate trade secrets and "commercially sensitive" data? How do secrecy clauses in the law need to be changed?

According to the statement factors which underlie excessive secrecy include:

- "*lack of legal obligation:* in some countries, the law establishing regulatory bodies does not impose on them any duty of providing information."
- "*lack of clarity in the law:* agencies or their staff may consider it safer to apply confidential clauses broadly rather than narrowly."
- "*lack of tradition:* many countries have no tradition of transparency in government."
- "*lack of consistent policy:* particularly in some developing countries there are (very) frequent changes in regulatory staff and general policy matters, such as the provision of information, receive little attention."
- "*absence of explicit routines:* within the agency, who is competent to release a particular type of information, to whom, and in what circumstances?"
- "*lack of capacity and resources:* particularly in under-resourced regulatory agencies, the time required to process requests for information may in itself be a barrier."
- "*paternalism:* the frequent belief that those outside of the agency do not need, could not cope with or would misinterpret the information."
- "*embarrassment:* an agency may hesitate to make fully public those decisions which are poorly documented or internally contested, papers which reflect poorly on the agency's performance, or matters on which it might be criticised for not yet having taken a decision."
- "*industrial influence:* many companies clearly prefer that entire regulatory files be regarded as secret."
- "*over-caution:* there may be an exaggerated fear of upsetting commercial susceptibilities."
- "*bureaucratic habit and inertia:* in agencies which are not subject to critical and transparent review, habits can form which discourage exchange of information."

The statement asserts that "Full availability of information is essential if all parties involved in health care are to participate effectively. Openness facilitates adequate feedback, proper setting of priorities and development of trust. A culture of openness protects conscientious individuals working in organizations of all kinds. Knowledge relating to all drugs evolves constantly, as do standards and expectations relating to them, their producers and health care providers. However thorough the investigations made before a drug is licensed and marketed, much more will be learned about its efficacy, proper use and risks once it is marketed and used on a much larger scale."

While the experts agree that some legitimate business secrets deserve to be protected, they stress the need to limit and define the type of data which should be protected on the grounds of commercial or patient confidentiality so that this privilege is not abused.

The statement highlights the need for drug regulatory agencies to reaffirm their commitment to protecting the public interest by making more information available about their decisions and decision making process. ❑

Copies of the ***Statement of the International Working Group on Transparency and Accountability in Drug Regulation*** *are available in English, French, Portuguese and Spanish, and can be obtained from HAI-Europe, Jacob van Lennepkade 334-T, 1053 NJ Amsterdam, the Netherlands. Tel: +31 20 683 3684, fax: +31 20 685 5002, e-mail: hai@hai.antenna.nl*

Examples of the types of information to which access is needed

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Availability of information must extend not only to data reaching the agency from the outside, but also to its own deliberations, conclusions and actions. Some examples of the type of documents and data which can be of particular value and can be made available without undue effort are given below. The list is not exhaustive and the general principle of full availability of all data continues to apply.

- Public assessment reports providing the essential reasons underlying the licensing of a drug and any conditions attached to the licence, or relating to the modification of an existing licence. Where an agency has not compiled reports for these specific purposes, its own internal assessment reports must be made available.
- Copies of the pharmacological, toxicological and clinical reports submitted to obtain the initial or modified registration of a drug and those added to the file subsequently.
- All of these reports should be accessible, anywhere in the world, from the date of marketing, (as should the texts of the approved data sheet and package insert).
- Inspection reports of pharmaceutical plants, subject only to the deletion of personal details and material details relating to industrial secrets and individual privacy.
- Adverse drug reaction reports received from health workers, manufacturers or other agencies, subject only to the deletion of personal data.
- Collected pharmacoepidemiology data including data on drug sales and drug consumption.
- The internal evaluation of the relevant regulatory authority regarding current adverse drug reaction reports.
- Where essential drugs lists exist: publication of motivated decisions to include particular drugs on the list or to amend the list.
- Reports relevant to the suspension, restriction or withdrawal of drug product licences or of manufacturing licences.
- Reports on agency meetings, including meetings of scientific committees and hearings, subject to the deletion of personal data.

Source: Statement of the International Working Group on Transparency and Accountability in Drug Regulation.

Patients' rights kit launched

CONSUMERS International has produced a kit entitled *Campaigning for Patients' Rights*. The aim of the kit is to help consumer and other interested organizations develop patients' rights guidelines, charters and laws, and in assessing quality standards in health care services.

The campaign materials are based on a 10-point charter of basic rights. These include: appropriate and accessible health care; freedom from discrimination; information and education; and informed consent about treatment. The charter is a distillation of the common elements of existing patients' charters, refined after consultation with members groups within Consumers International.

The kit includes a colour poster of the charter; an attractive leaflet for general use, which lists the 10 rights; a guide for patients and consumer activists designed to help organize debates, and plan strategies for involving individuals and groups in promoting patients' rights; a short training manual for assessing health care; and a list of ongoing national activities on patients' rights.

The full kit is available, free of charge, to NGOs, as are up to 50 copies of the poster and leaflet in English, French, Spanish or Russian. If groups require a larger supply of the materials Consumers International can reproduce them at cost. ❑

The kit includes a 10-point charter of basic rights

For further information contact: Consumers International, Regional Office for Asia and the Pacific, P.O. Box 1045, 10830, Penang, Malaysia.

Collaboration speeds post-war pharmaceutical reform process

A situation analysis of the pharmaceutical sector in Bosnia and Herzegovina and the Republika Srpska was carried out in July 1996 by a team from the Programme for Pharmaceuticals of WHO's Regional Office for Europe, in collaboration with the Ministries of Health. Its findings have been made available to national decision makers, managers and key professionals in the pharmaceutical sector.

Working groups for pharmaceutical reform have been set up by the Ministries of Health of Bosnia, Herzegovina and Republika Srpska, with WHO support. The groups will develop and implement pharmaceutical policies in each country. Draft strategic plans are being drawn up to define priority objectives and how they can be achieved, and these should be finalised by spring 1997.

Drug legislation and regulations, and quality assurance systems were among key areas identified for technical collaboration between WHO and the Ministries. Expert groups have already reviewed the drug legislation and regulations used in the pre-war period, with the aim of modernising them in line with international standards. A structure for pharmaceutical policy management and regulatory enforcement is to be created. This will be crucial in ensuring the availability of safe, effective, good quality drugs for the population. ❑

A first for Pacific Island Nations

RECOGNITION of the limited attention devoted to specific drug issues for the Pacific Island Nations, and how these might be addressed on an individual country and regional basis, led to the Seminar on National Drug Policies for the Pacific Island Nations held in Nadi, Fiji, from 9–11 September 1996. Consumers International Regional Office for Asia and the Pacific sponsored the event, in collaboration with the Ministry of Health in Fiji and the South Pacific Consumer Protection Programme.

The seminar brought together representatives from health ministries and consumer organizations from 14 Pacific Island Nations, including American Samoa, Cook Islands, Federated States of Micronesia, Fiji, Kiribati, Marshall Islands, Northern Marianas, Palau, Papua New Guinea, Solomon Islands, Tonga, Tuvalu, Vanuatu and Western Samoa. Resource persons came from Australia, Malaysia, New Zealand and the Philippines. Discussions centred on how:

- to build cooperation and mutual support in the development of national drug policies in the Region;
- to share detailed information regarding the drug situation in the Pacific Region including drug policies, drug availability, drug supply logistics and drug usage;
- to identify the major constraints in the pharmaceutical sector to improvement of the drug situation and to implementation of national drug policies;
- to develop strategies to improve the drug situation and incorporate these into action plans for their implementation.

The meeting concluded that experience from several countries has shown how campaigns to promote the rational use of drugs and to implement national drug policies succeed when health ministry officials (providers) and consumers work closely together.

To build on the progress made at the seminar, and based on its recommendations and those from the Conference of the Ministers of Health of the Pacific Islands held in March 1995 (contained in the Yanuca Island Declaration), WHO's Regional Office for the Western Pacific plans to hold a workshop on drug supply management and drug quality assurance in the Pacific Islands in November 1997. Final details are still to be confirmed but will be included in EDM-23. ❑

For further information on the seminar contact: Consumers International, Regional Office for Asia and the Pacific, P.O. Box 1045, 10830 Penang, Malaysia. Tel: + 60 4 229 1396, fax: + 60 4 228 6506, e-mail: ciroap@pc.jaring.my

India's doctors warned on irrational prescribing

CONSUMER health groups in India have told doctors to prescribe drugs rationally or be prepared to be sued in consumer courts for medical negligence. The warning was issued through a press conference in December 1995 given by a consortium of nongovernmental organizations. It follows a survey of prescriptions which the group says showed cases of "alarming, completely irrational prescribing".

The survey, conducted by the Voluntary Consumer Action Network (which includes around 20 consumer and health organizations), showed that many doctors prescribe tonics, vitamin formulations and expensive drugs, including third generation antibiotics, when they are not indicated. General practitioners and consultants tend to prescribe "unnecessary drugs like antibiotics for all diarrhoeas, cough mixtures for the common cold and anabolic steroids in contraindicated cases", according to the survey report. Incidents included prescriptions for three or four drugs without specific indications, and overdosage of potentially toxic drugs, such as antimalarials, for all types of fevers. The survey showed that doctors in private practice tend to be the worst offenders in irrational prescribing.

Dangerous trends...

The findings were based on an analysis of some 2,000 prescriptions collected directly from patients in six Indian states. Krishnagshu Ray, Professor of Pharmacology at the National Medical College in Calcutta, who helped to analyse the prescriptions, admits that the sample size is too small for the results to be extrapolated for the entire country. "But these preliminary results confirm lingering suspicions of irrational drug use and reveal dangerous trends that need to be checked", said Professor Ray. "The findings also suggest that continuing medical education programmes for medical professionals are not as effective as they should be", he continued.

The consumer groups claim that pharmaceutical companies have a key role in influencing the choice of drugs prescribed. They assert that many doctors believe India lacks sources of unbiased information on drugs. "There are no mechanisms to make available to prescribers periodic research-based advice leaflets relevant to local needs, nor is there any encouragement to evolve such mechanisms," said Ashok Rattan, Associate Professor of Microbiology at the All India Institute of Medical Sciences in New Delhi. In the early 1990s Indian microbiologists attributed outbreaks of *Salmonella typhi*, resistant to many drugs, to the widespread abuse of antibiotics. "The abuse of antibiotics is still rampant", said Rattan.

The Voluntary Consumer Action Network will watch doctors whose prescribing they believe to be questionable. If necessary, they will file cases against them in special consumer courts where patients can claim damages from doctors who charge for their services. The group plans to use the results of the survey to campaign for a prescription audit system in all Indian states. Another nongovernmental organization, the Foundation for Health Action, is relying on informal channels to compile a national database on adverse drug reactions resulting from inadequate prescribing. ❑

Source: British Medical Journal, vol. 312, 13 January 1996.

Consumer groups in India are now prepared to go to court in their campaign to end irrational prescribing. They want all doctors to follow the example of the one shown here giving essential drugs to a patient

Photo: WHO/C. Stauffer

Teaching good prescribing in twelve languages

WHO's *Guide to Good Prescribing* provides a step-by-step, problem-oriented approach to training in rational, responsible prescribing (see EDM-20). It is clearly meeting a deep-felt need with plans well advanced for editions in 11 languages, in addition to the original English:

- a WHO French edition is in press;
- WHO's Regional Office for the Eastern Mediterranean will issue an Arabic edition;
- a Russian translation exists in manuscript and will soon be published within the context of collaborative work in the Russian Federation and states of the former Soviet Union;
- a Mongolian edition has been published by the Ministry of Health;
- a Japanese edition is nearly finalised and will be issued by a commercial company with royalties to WHO;
- educational publishers in Europe and Latin America have been granted rights to produce editions in German, Italian, Polish, Portuguese, Romanian and Spanish. These editions should be available in l997;
- a very low cost English edition has been published, with DAP authorisation, by an Indian NGO, making it highly accessible to potential users on the sub-continent.

A copy of the full text is now also available electronically through a link between DAP's homepage on World-Wide-Web and the web site of Groningen University, where the methodology was originally developed (see Netscan, page 16). ❑

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

Improving international coordination in pharmaceuticals

REPRESENTATIVES of UNICEF, WHO/DAP, the World Bank and European Union met in Stockholm in September 1996, to discuss how global and country level coordination in the pharmaceutical sector could be improved. The group focused on identifying technical and policy issues where differing agency positions cause problems at the country level, and on better understanding constraints faced by multilateral agencies, particularly those relating to drug procurement and supply.

Hosted by SIDA, this was the first in what are expected to be regular meetings aimed at strengthening interagency coordination in pharmaceuticals. Several of the organizations had also participated in earlier meetings (February l996 in Washington hosted by the World Bank, and April 1996 in Geneva hosted by WHO), which focused on evolving roles in the pharmaceutical sector.

During the discussions each of the four agencies summarised its main areas of work, strengths, weaknesses and major challenges ahead. Eight examples of country-level coordination experiences – both positive and negative – provided practical illustrations of common problems and potential solutions. Participants identified similarities and differences in major policy issues. The meeting concluded with agreed follow-up actions, including mechanisms for ongoing coordination. Priority areas for the coming six months included drug pricing and registration; drug financing; procurement capacity building; and public education on rational drug use.

WHO/DAP will organize and host the next meeting of the coordination group, to be held in Geneva in March 1997. ❑

Malaysia: improving public education on drug use

MALAYSIA is taking decisive steps to improve the way it educates consumers about drug use. Closer collaboration is seen as a key to success, as shown by a national workshop on the subject organized jointly by the Ministries of Health, Education and Information, the Malaysian Pharmaceutical Trade and Manufacturers Association, and the Malaysian Pharmaceutical Society. Attended by 30 representatives from various governmental and nongovernmental agencies, the workshop was held in Seangor in December 1995, and was the first collaborative activity of its kind, reports Consumers International.

Over two days participants discussed strategies for campaigns on consumer education on rational drug use and drew up plans for future activities. Recommendations from the meeting included: expanding the existing committee on consumer education on drug use, which is responsible for planning and implementing activities; setting up a task force to raise funds and help implement the activities; and increasing the effectiveness of the proposed educational interventions. Involvement of both the public and private sectors, nongovernmental organizations, consumer groups and the media was seen as vital for success. ❑

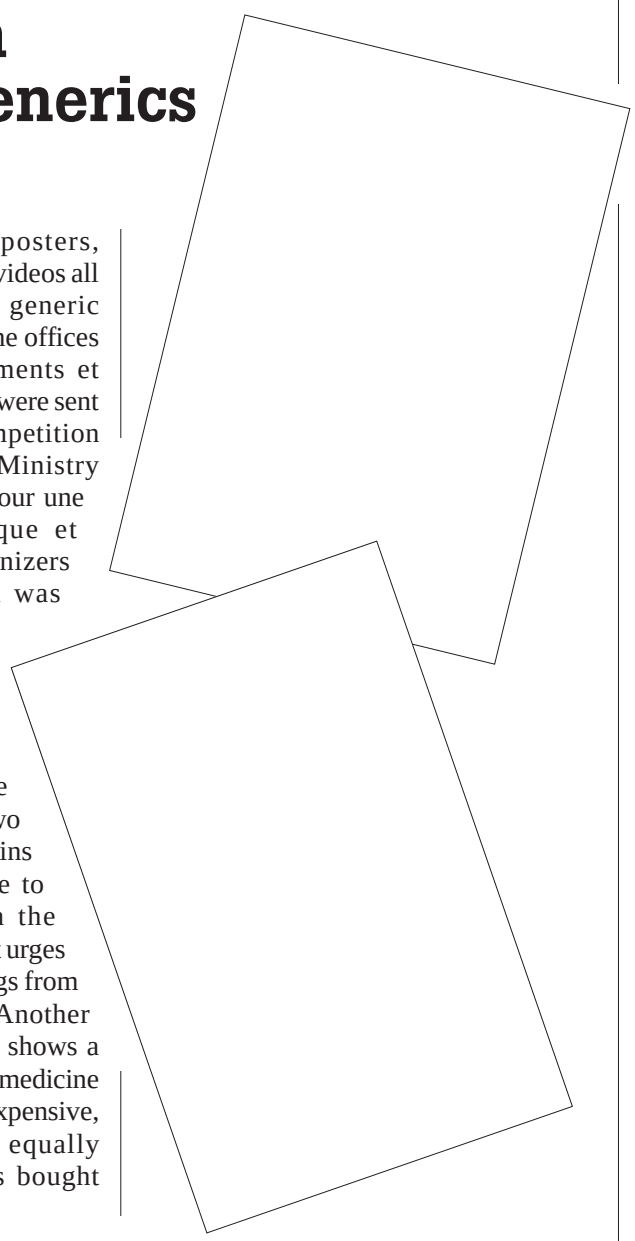
AFRO intensifies Essential Drugs Programme

WHO's Regional Office for Africa has developed a plan for an intensified AFRO Essential Drugs Programme, with input from DAP. The plan builds on several sub-regional activities and covers four major areas: (1) drug procurement; (2) a market intelligence database; (3) drug regulatory authorities and quality assurance systems; and (4) institutional support to AFRO to strengthen management capacity for the proposed programme. The five-year budget to implement this programme amounts to US$ 7.5 million. A detailed proposal has been submitted to a number of donors and a donor meeting is planned for early 1997. Discussions at a Regional Consultation on Essential Drugs Procurement contributed to the development of the programme proposal. The Consultation brought together donor agencies and 10 AFRO Member States, in the Regional Office for Africa in April 1996.

The principal objectives were to identify and propose solutions for the major problems faced by participating countries in the drug sector. Topics discussed included: the supply and availability of essential drugs in Africa; strengthening drug regulatory authorities and quality assurance systems; developing, implementing and monitoring national drug policies; and promoting regional and international cooperation. ❑

Competition promotes generics in Africa

OVER the last months posters, slogans, radio clips and videos all promoting the use of generic drugs have been pouring in to the offices of ReMeD (Réseau Médicaments et Développement) in Paris. They were sent by hopeful entrants in a competition run by ReMeD, the French Ministry of Cooperation and PIMED (Pour une Information médicale éthique et le Développment). The organizers saw the competition, which was open to all African residents, as an innovative way of stimulating interest in generics.



Finally, the winners have been announced. The first prize (see top illustration) describes two samples of medicine as "like twins in different clothes" both able to relieve symptoms, but with the generic medicine costing less. It urges everyone to request generic drugs from their doctor or pharmacist. Another winning entry (see illustration) shows a mother, who, on hearing that the medicine needed for her sick child is too expensive, insists that the cheaper but equally effective generic medicine is bought immediately. ❑

Workshop reinforces rational use message in India

STIMULATED by the quality of debate and the opportunity to exchange ideas and experiences, participants left a three-day workshop in Bangalore with renewed enthusiasm to continue promoting the rational use of drugs. Organized by the Catholic Health Association of India in July 1996, the workshop was attended by pharmacists, doctors, nurses and administrators from the southern states of Andhra Pradesh, Karnataka, Kerala and Tamil Nadu.

Wide-ranging discussions covered essential drugs, rational use of drugs at different health care levels, prescription audit, non drug therapies and drug marketing. Participants agreed on the need for: therapeutic committees to be established in hospitals; pooled drug procurement; regular meetings between dispensers and prescribers; and efficient dissemination of drug information. ❑

For further information contact: The Catholic Health Association of India, PB 2126, Gunrock Enclave, Secunderabad AP 500 003, India. Tel: +91 848293, fax: +91 040 811982, e-mail: chai@giasbm 01.vsnl.net.in

New WHO TB newsletter

NOVEMBER 1996 saw the launch of WHO's latest newsletter, *The TB Treatment Observer*, issued by the Global Tuberculosis Programme. Designed as a quarterly newspaper, *The Observer* focuses on Directly-Observed-Treatment, Short-course (DOTS) as the most effective method of preventing the spread of TB today. It illustrates the DOTS strategy using feature articles on DOTS' country successes, data on cure rates from DOTS and non DOTS projects, and forecast data on the effects of HIV and multidrug resistant TB on the TB epidemic. By helping to familiarise policy makers, managers and health staff of TB control programmes in developing countries with all aspects of the DOTS strategy, WHO hopes that *The Observer* will motivate people to start using the strategy and strengthen the political commitment necessary for its expansion. ❑

For further information or to obtain a copy of the newsletter, please contact: Managing Editor, The Observer, Global Tuberculosis Programme, World Health Organization, 1211 Geneva 27, Switzerland.

Indicators for monitoring NDP: computerised programme available

THE DAP manual, *Indicators for Monitoring National Drug Policies*, produced in 1994, has been used in many countries. To assist with data entry and calculating the indicators, DAP has prepared a diskette which contains the four categories of indicators described in the manual – background, structural, process and outcome indicators. It also contains space to include other indicators added at national level. The software used is Excel 5.0 for Windows and the diskette is still being field tested. ❑

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

Consumer group seminar focuses on trade issues

THE high level of interest in how recent international trade agreements and the creation of the World Trade Organization (WTO) will affect the pharmaceutical sector was reflected by the popularity of a seminar organized by HAI-Europe and BUKO Pharma-Kampagne. Held in Bielefeld, Germany, in October 1996, the one-day meeting on GATT/WTO, Pharmaceutical Policies and Essential Drugs, attracted more than 50 participants from l7 countries, including researchers, health activists, representatives from international organizations (including the Action Programme on Essential Drugs), consumer groups and the pharmaceutical industry, as well as members of the German press. The aim of the seminar was to provide a better understanding of the mandate of the World Trade Organization, of the implications for members and of GATT/WTO and its conseqences in the pharmaceutical sector. Speakers included representatives from WHO, WTO, and various individuals involved in consumer rights, health and development issues.

National and international consumers' organizations have been working for many years to ensure that consumers benefit from international trade. This work has included conducting research and lobbying international trade bodies. Consumers International, for example, has stated that the formation and work of WTO will be a major focus of its policy and campaign work. Its l994 publication, *Unpacking the GATT* (see Published Lately), provides a clear introduction to the Agreement from a consumer perspective, together with an analysis of the implications of the Agreement, particularly with respect to developing countries. Consumers International argues that a major flaw in the Agreement is the lack of provision for the involvement of other interested parties, such as consumer organizations, in the working of the WTO.

In response to interest expressed at the Bielefeld seminar, HAI has organized a working group to take forward various projects involving trade and pharmaceuticals. ❑

For further information or to obtain a copy of the proceedings of the meeting contact: Health Action International-Europe, Jacob van Lennepkade 334-T, 1053 NJ, Amsterdam, the Netherlands. Tel: +31 20 683 3684, fax: +31 20 685 5002, e-mail: hai@hai.antenna.nl

Essential drugs list for India

INDIA'S first essential drugs list has just been published and is intended to provide a guideline to rational therapeutics. Although not mandatory for public or private sector, the list has been widely circulated. Copies have been sent to the Secretaries of Health of the States and Union Territories for use in the public sector. In the private sector the list is being promoted through national associations, such as the Indian Medical and Pharmaceutical Associations, which have extensive networks throughout the country.

The list uses generic names for scientific clarity. The drugs were selected "to meet common contemporary health needs" taking into account such factors as safety, cost-benefit, availability at an affordable price and experience with use.

Drawing on the WHO Model List of Essential Drugs and the general principles recommended by WHO, the Indian national list was prepared by a committee representing a wide range of disciplines. It will be regularly reviewed. ❑

Available from: Dr P. Das Gupta, Drugs Controller General (India), Directorate General Health Services, Nirman Bhaven, New Delhi – 110 001, India. Tel: +3018806, fax: +3017924.

Drug Information Association offers research grants

THE Drug Information Association's Research Grant Programme aims to encourage and foster research in areas related to pharmaceutical and biotechnology product development, regulation, marketing, use and surveillance. One-year grants of up to US$ 25,000 are available through the Programme. They are awarded on criteria which include: the quality of the proposed research, the research personnel's qualifications, and the subject's relevance to the Association's goals and interests.

Applicants for research grants must be affiliated to not-for-profit organizations and applications should be received before 1 February each year for funding to begin in September. ❑

For further information contact: Drug Information Association, 321 Norristown Road, Suite 225, Ambler, PA 19002-2755, USA. Tel: +215 628 2288, fax: +215 641 1229; e-mail: dia@diahome.org

Devaluation of the CFA franc: an update

THE l994 CFA devaluation (see EDM 18 and 19) created a surge of interest by affected countries in essential drugs policies. This has now been concretised in a collaborative approach to issues of rational drug procurement and use by ministries of health of 20 CFA and associated countries. Six technical working groups – with a plan of action and a budget – have been set up to tackle key issues. And a general coordinating secretariat has been established in Côte d'Ivoire. Regional collaboration is being reinforced at the international level through support from the Action Programme on Essential Drugs.

Each group's focus and current activities are summarised below:

- ***drug procurement and quality*** (coordinated by Benin), is working on model tendering documents and mechanisms for central medical stores;
- ***drug market intelligence*** (coordinated by Côte d'Ivoire), is collecting data from 11 countries on market intelligence;
- ***generic essential drugs in the private sector*** (coordinated by Central African Republic), started with a workshop in Douala, Cameroon, on generic drugs in the African private sector. The five-day meeting brought together a multidisciplinary group of 70 participants from 14 countries;
- ***adaptation of drug regulation*** (coordinated by Burkina Faso), is working on harmonisation of registration criteria and procedures for registering generic drugs;
- ***promotion of better prescribing and dispensing*** (coordinated by Mali), is surveying prescribing and dispensing practices and collecting training materials in member countries;
- ***promotion of local production*** (coordinated by Senegal), is not yet active. ❑

Photo: WHO/P. Pittet

A doctor writes a prescription for his patient in Mali, which is coordinating promotion of better prescribing and dispensing among the CFA countries

NATIONAL DRUG POLICY

DAP support – making a difference in Guinea

Karin Timmermans*

PROVIDING direct country support has always been one of the Action Programme on Essential Drugs' key roles. No standard formula exists for such support and the Programme's involvement depends on a country's situation, its specific problems, priorities and objectives. The Republic of Guinea provides an example of what DAP assistance, even with limited funds, can help to achieve.

Finding solutions in a crisis situation

Until 1984 Guinea's pharmaceutical sector was characterised by State monopoly in drug production, distribution and dispensing. With the change of regime in 1984 structures broke down, and in the health sector nothing appeared "spontaneously" to replace them. By 1986, when DAP began its cooperation with Guinea, there were virtually no drugs. So while the public sector existed in theory it could not function. And there was no private sector, as private initiative had been discouraged.

Faced with such huge problems, the new Government opted for a dual approach – opening up the health sector to private enterprise and restructuring the public sector. Ten years later, the changes are dramatic: over 80% of all sub-districts have a functioning health centre, there are a large number of private pharmacies in urban areas and drugs are available. Important tools have been put in place, including a National Drug Policy, an Essential Drugs List, a National Formulary, and modules to teach medical and pharmacy students about the essential drugs concept.

In 1995 a study of the pharmaceutical sector was undertaken, with DAP technical and financial support. The study, which used an objective system of indicators (see Table), concluded that:

- the systems and tools necessary to make a national drug policy work – such as an up-to-date pharmaceutical law – exist in Guinea, with the exception of some of those related to quality assurance (see below);
- however, the systems which have been put in place are not yet fully operational, or are not performing optimally;
- in the public sector, levels of availability, affordability and rational prescribing (standard treatments) are good but drug quality is not controlled. This is linked to the fact that there are no quality control laboratories, and, although Guinea is a signatory to the WHO Certification Scheme on the Quality of Pharmaceutical Products moving in International Commerce, the Scheme is not used systematically.
- in the private sector, availability is satisfactory (pharmacies are well stocked but located only in urban areas), drugs are used rationally, however, affordability and quality remain problematic;
- in the parallel market, availability is only moderate, quality is problematic, but drugs are affordable, so this sector is flourishing.

In 1986 identifying the main problem in the pharmaceutical sector was not difficult – due to the total absence of drugs, questions of price, quality and rational use were irrelevant. In such situations it is easy to think that the solution is as simple as the problem – "let's start bringing in the drugs, and then settle the rest". With DAP's help Guinea has generally avoided this mistake in the public sector, but has had less success in the private sector.

The public sector: focusing on primary health care

To tackle the lack of health care provision and drug shortages, the Government created a primary health care programme based on: improvement of the infrastructure; community involvement; a cost recovery system; preventive as well as curative care; rational use of essential drugs; and staff training.

Focusing on rural health centres, with donor support for equipment and an initial drug donation for each new health centre (mainly from UNICEF), and with technical and financial assistance from WHO and UNICEF, the programme has expanded under its own impetus. It has attracted an increasing number of communities wanting to create their own health centre within the programme umbrella. Multilateral, bilateral organizations, NGOs, and the health structures they support, also became involved.

Within the primary health care programme, a specialist unit was temporarily created to deal with drug importation and distribution, while the central medical store and its depots were modernised with support from the African Development Bank.

When putting the programme in place, a decision was made to link drug availability to affordability and rational use. The aim was to provide a limited number of essential drugs at prices that could assure their continuing availability, while also ensuring that most people could afford them. This has led to nationally standardised prices fixed by the Ministry of Health and to an Essential Drugs List, a formulary and flow charts for standardised treatment.

Photo: M. Everard

Patients wait for their drugs prescribed by a health centre doctor. In Guinea's public health sector drugs are now more readily available

To ensure that Government directives were followed, staff training on the programme's basic principles was given before a health centre joined the system. This was followed by regular monitoring exercises.

A growing private sector

To stimulate private initiative, the Government tried to create favourable conditions (high profit margins), which after a slow start led to a huge expansion of private pharmacies, resulting in increased drug availability. The growth in number of facilities and drug availability are common to the public and private sectors, however, significant differences remain between the two sectors. Private pharmacies are exclusively in urban areas (with a disproportionately large number in the capital), and the majority of the population cannot afford their drugs. Reasons for the high prices include pharmacists' fixation with brand name products, high profit margins (set initially to stimulate private investment), and the near monopoly of the largest wholesaler. High prices, combined with a population that – after the shortages of the past – insists on drug treatments for its ailments, have provided fertile ground for the development of a parallel drug market.

As the Ministry of Health had no experience of how to regulate or manage a private sector, at first its intervention was limited to registration of private pharmacies and wholesalers. With the help of the African Development Bank and DAP this is slowly changing and the sector is being regulated. Pharmaceutical legislation has been updated; since 1994 generic drugs (that previously could only be sold in the public sector) have been allowed in the private sector; pharmaceutical inspectors have received additional training and are starting their inspections; and criteria and procedures for drug registration have been established.

DAP's role in Guinea

Over the last 10 years, when so many activities have taken place and so many partners have been involved in the pharmaceutical sector, what has DAP's role been? And what, if anything, has set DAP apart from other organizations? Looking back, what stands out – apart from its financing of some activities – are DAP's coordinating, advising and evaluating roles.

- ***Coordinating***

  Contrary to what might be expected, DAP's coordinating role has never been very high profile. It could not be, as DAP has never been the 'lead' nor the major donor, the executing agency, nor the official coordinator. Instead, coordination of the various interventions and the different groups was more subtle: by advising, and sometimes warning, the Ministry of Health; and by focusing DAP support on a few key activities that others overlooked, did not want or were unable to carry out, but that facilitated the success of other interventions.

- ***Advising***

  Many DAP consultants and staff have advised the Ministry of Health on drug related subjects during the preparation and implementation of the primary health care programme, and on topics related to the private sector. They have also highlighted potential problem areas and bottlenecks in the system. Technical assistance has been

cont'd on pg. 8

DAP support... cont'd from pg. 7

given to the primary health care programme's essential drugs unit and the Ministry of Health's Department of Pharmaceutical and Laboratory Services.

➤ ***Evaluating/steering***

Evaluation has been a regular aspect of DAP support – but where others asked "What have we done?", DAP posed the broader question "What has been done?". In accordance with the NDP's objectives, evaluation of the pharmaceutical sector helped the Ministry to steer and retain control of developments. The evaluations also helped to create awareness within the Ministry of its own role in the pharmaceutical sector and how to execute that role.

Helping the Ministry to stay in control and work towards the drug sector's coherent development has set DAP support apart from that of other organizations and made it much appreciated by the Ministry.

Indicators of the drug situation in Guinea in 1995*

Indicators	Results	by sector
Availability of drugs		
Percentage of a selection of essential drugs available in remote health centres	93 %	public
Percentage of a selection of essential drugs available as generics in private pharmacies	33 %	private
Affordability of drugs		
Cost of a treatment of pneumonia for 1 person as percentage of the cost of food for an average family of 8–10 people, for 1 day	26 % 166 % 29 %	public private market **
Average price of a selection of essential drugs in generic form, compared to the price of brand name equivalents	20 %	private
Quality of drugs		
Percentage of drugs that failed quality control testing	23 % 19 % 24 %	public private market **
Percentage of drugs on the shelves that are beyond their expiry date	0.7 % 0 %	public private
Rational use of drugs		
Average number of drugs per prescription	2.40 2.08 2.53	public private market **
Percentage of prescriptions with injections	20 % 21 % 34 %	public private market **
Percentage of children under 5 years with diarrhoea, who receive antidiarrhoeal drugs (and percentage who receive Oral Rehydration Solution (ORS))	15 % (96 % ORS)	public
Percentage of drugs that are on the national essential drugs list, from the 50 best selling drugs in the private sector	26 %	private

* *Research on the implementation of the National Drug Policy, Conakry, May 1996*
** *Parallel market*

More challenges ahead

Due to limited staffing levels, time and funds, not all problems have been solved. Drug quality in the public and private sectors is a source of concern in a country without the resources to carry out quality control tests. The consistently high prices in private pharmacies are another worry. Allowing the private sector to sell generic products was a first step to make drugs more affordable but real incentives to promote generics have yet to be implemented.

There is an urgent need for the recently modernised central medical stores to become an efficient and dynamic organization, capable of purchasing and supplying good quality essential drugs at competitive prices.

Recent six-monthly monitoring exercises to evaluate health centres' medical and financial performance have shown some underuse of facilities. This leads to as yet unanswered questions: are people unaware that these health centres exist? are they still too expensive for some people? are people reluctant to go to a Government related health institution? are people dissatisfied with the services they receive? or do they lack confidence in 'western' medicine?

In the battle against inappropriate drug use and an uncontrolled parallel market other problems still need to be addressed. They include: lack of information on and control over drug importation; weak cooperation between the Ministry of Health and other Government departments, such as Customs; insufficient resources for the inspection system to function and to implement sanctions; and little consumer understanding of the risks of irrational drug use.

The Ministry is aware of these problems and their importance, and Guinea hopes that international efforts to improve the pharmaceutical sector will be maintained. DAP will continue its support to Guinea, with a focus on strengthening management and regulatory capacities at central and regional levels.

In a country with very limited resources and infrastructure, compounded by a lack of trained staff, pharmaceutical reform is a difficult and time consuming process. Even when most of the infrastructure, tools and systems are finally in place, some problems will inevitably persist and attention should shift to them: an adequate operating budget, staff motivation and political will are essential for further improvements to be made. To succeed, it needs a coordinated effort and international support. In such situations, DAP support, even if limited, can make a difference. DAP has undeniably helped Guinea in filling some of the gaps and has become a real partner to the Ministry of Health. ❑

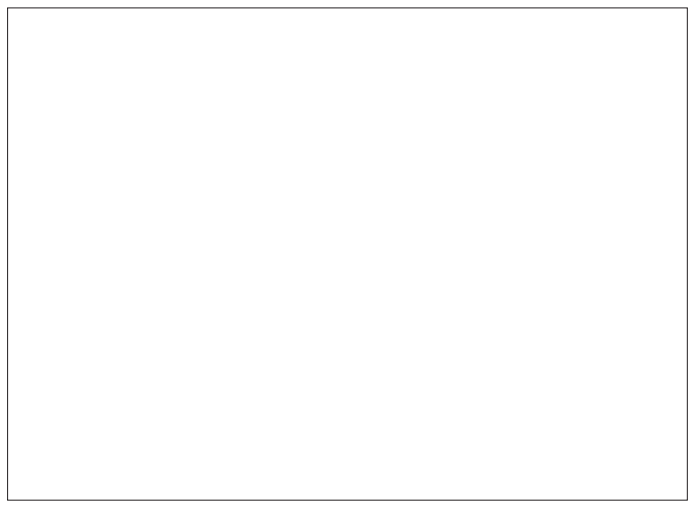


Photo: M. Everard

The health centre at Tongnifily, Guinea, built and paid for by the local community, shows what local involvement in primary health care can achieve

* *Karin Timmermans is a pharmacist whose work for WHO has included 3 years in the Essential Drugs Programme in Guinea.*

1. The illegal private market

Comparing national drug policies: important new data

THE research project on national drug policies, developed jointly by the Action Programme on Essential Drugs, the Karolinska Institute and the Harvard School of Public Health, aims to assess the performance of national drug policies in developing countries, to analyse the reasons for their success or failure and to draw lessons for future action (see EDM-19).

The project was first introduced to researchers from the eight participating countries during a workshop held in Geneva in October 1994. They prepared individual country research protocols, and trained in the two project research methods: application of a standard set of indicators[1] and political mapping.

At a follow up workshop in Geneva in June 1996, 25 researchers reviewed preliminary findings, tackled any methodological problems and planned completion of the project. Participants included researchers from Colombia, Guinea, India, the Philippines, Thailand, Viet Nam, Zambia and Zimbabwe; observers from countries which have implemented the WHO indicators for monitoring national drug policies: Bulgaria, Chad and Mali; and resource persons from the three collaborating institutions.

This was one of the first occasions for countries to compare standardised data and discuss cross-national variations in NDP performance. It showed the importance of monitoring and comparative analysis, and highlighted the relevance and usefulness of the WHO indicators for monitoring national drug policies. A user guide to assist in applying the WHO indicators will soon be available, and research findings will be widely disseminated. ❑

A report of the workshop is available from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland.

Reference

1. Brudon-Jakobowicz P, Rainhorn JD, Reich MR. Indicators for monitoring national drug policies, WHO/DAP/94.12. Geneva: World Health Organization, Action Programme on Essential Drugs, 1994

Pharmaceutical project in Chad

DAP is providing technical support to the Government of Chad in the implementation of a pharmaceutical project, which started in May 1995. Several activities have been implemented by the project since then: formulation of a national drug policy and a pharmaceutical master plan, revision of the list of essential drugs, drug legislation and regulations, strengthening the drug registration and pharmacy inspection services, and a baseline study on national drug policy indicators. Reviews will be jointly conducted by the Government, the World Bank and DAP. Another study will be conducted at the end of the four-year project to assess the impact of the project. ❑

NATIONAL DRUG POLICY

Iran: an evolving National Drug Policy

R. Dinarvand*

SINCE the Islamic revolution in Iran 18 years ago, one of the Government's main priorities has been to ensure the availability of medicines. Previously almost 75% of drugs were imported, with the remaining 25% produced locally, mainly under licence from multinational companies. Today, approximately 97% of drugs used are produced by Iranian companies. The remaining 3% are imported, because for technical or financial reasons they cannot be manufactured locally. People can obtain their medicines from more than 2,000 health centre pharmacies, 3,400 private pharmacies and 800 hospital pharmacies. Prescription medicines are only dispensed by pharmacists.

After the revolution, a national drug policy was developed with two basic aims: to ensure that drugs were available, accessible and affordable for the whole population; and to attain self-sufficiency in production. Measures taken to achieve these aims, included:

- basing the policy on the concept of generic products, with a ban on producing or importing proprietary drugs when a generic product is available;
- nationalising multinational pharmaceutical companies;
- organizing six pharmaceutical distribution companies, owned by pharmaceutical production companies, to distribute drugs and medical supplies to all areas of the country;
- centralising drug procurement and importation and limiting it to one company owned by the Ministry of Health (Iranian Pharmaceutical Incorporation). Another state company, (Daru Pakhsh), subsequently privatised, was allowed to import some drugs. Red Crescent was later allowed to import urgently needed drugs and medical supplies;
- allocating hard currency in the annual national budget to import pharmaceutical products and raw materials, regardless of the country's economic situation;
- limiting the list of drugs licensed for distribution. (Currently 1,150 drugs are registered, of which 225 are considered essential and receive Government subsidies of US$ 250 million).

During the years of war and economic sanctions in the eighties these strategies were considered fundamental to ensure the availability of drugs. But Iran's new economic policies in the nineties affected the pharmaceutical sector dramatically. All state-owned pharmaceutical manufacturers were privatised, although central planning has continued. The pharmaceutical companies need hard currency to import raw materials. This is allocated to each company by the Government, at a subsidised exchange rate, and is dependent on a production programme (type and quantity of products) agreed with the Department of Pharmaceutical Affairs, Ministry of Health. Through this mechanism the Government is able to guide national pharmaceutical production.

In addition to the allocation of hard currency at a reduced rate, many essential drugs receive further Government subsidy to keep their price low. In l995 this subsidy amounted to US$ 250 million. As a result, the price of drugs in Iran is much lower than in neighbouring countries.

Although the overall impact of the national drug policy has been positive, difficulties have also been encountered. These include drug shortages, the public's main concern; over-consumption of drugs; the low quality of some products; and drug smuggling to neighbouring countries.

New strategies for new times

To tackle the difficulties and also to respond to the new situation in the world and in the country, a national board was appointed in 1995 to revise the drug policy. The main priority of the National Drug Policy-Making Board (NDPMB) is to guarantee the availability and accessibility of high quality drugs for the whole population, taking into account the limitation of resources. The Board has 15 members drawn from all areas of the pharmaceutical sector including industry, importers, retailers, academics and representatives from the pharmaceutical administration, the regulatory body and the Iranian Pharmacists Association. Seven committees cover pharmaco-economics; research and development; rational use of drugs; industry; procurement and distribution; pharmaceutical raw materials; and medicinal plants and natural products. Each committee has between seven and 11 members and is chaired by a member of the Board. The measures introduced cover five principal areas:

Availability

The Government's main priority has always been to ensure an adequate drug supply. Steps taken by the NDPMB include: the allocation of hard currency for the pharmaceutical sector in the national budget; building new facilities for drug production; restricting the number of drugs in the market to a limited list of essential drugs, and most importantly, allocating a large sum of money to subsidise the price of 225 drug dosage forms, to keep their price down. Previously this subsidy was paid to the pharmaceutical production companies. In l995, however, it was decided to pay the subsidy to the pharmaceutical distribution companies to free the industry from dependence on the Government. The next step will be to transfer the subsidy to the health insurance system when coverage is nationwide. Since the Government has committed itself to develop a national health insurance system covering the whole population, a reduction in the drug subsidy to the distribution companies is being planned for next year.

Quality and efficiency

The pharmaceutical regulatory and quality control authorities in Iran are well established and functional, however, some problems of drug quality and efficacy remained and were addressed. It is now compulsory for all pharmaceutical companies to provide bioavailability, bioequivalence and clinical trial data when applying for licence registration or renewals. Another important measure introduced by the NDPMB was to incorporate 1% of a drug's factory price in the approved finished price, to be allocated solely for research and development. This may be used to improve drug formulation quality according to Board guidelines, and is additional to the companies' research and development budget.

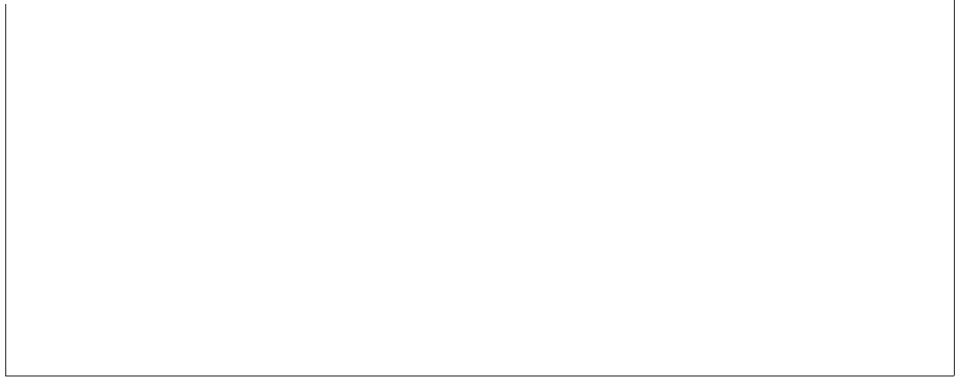


Photo: WHO/D. Deñaz

Technicians at a pharmaceutical laboratory in Iran. The Government's main priority in the pharmaceutical sector has been to ensure an adequate supply of good quality drugs

Rational use

The Board recognised that the most effective way to rationalise drug use is to improve how physicians prescribe. Plans are now underway for a drug prescription control committee to be set up in each province, with a computer link to a national committee in Tehran which would oversee the scheme. Provincial committees will consist of curative and pharmaceutical affairs authorities in the province; three specialist physicians (from academia); one specialist physician from the Medical Association branch in the province; and one pharmacist, all appointed by the chancellor of the local medical university and health services. Prescriptions will be collected through health insurance companies, which will pay the committee's expenses. At least once a year all doctors will receive a report of their prescribing behaviour and advice on how to improve, if necessary.

Initial data from a pilot project in two provinces confirm the effectiveness of this approach. They show that over-prescription of drugs was reduced. It is estimated that a national audit scheme could potentially save the country at least 10% of its current drug budget. More importantly, it would save many people from the side effects of unnecessary drugs (see Figure).

Self-sufficiency

While only 3% of the finished medical products used in Iran are imported – the remaining 97% of drugs are formulated in the country – almost all the raw materials are imported. Local production of raw materials is now being boosted through:

- the allocation of at least 5% of the total pharmaceutical sector currency budget to private companies for technology transfer and necessary equipment;

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Iran NDP... cont'd from pg. 9

- prohibiting import of raw materials which are locally produced and which have had their quality assured by the Ministry of Health;
- guaranteeing a market and reasonable price for the first producer of each raw material.

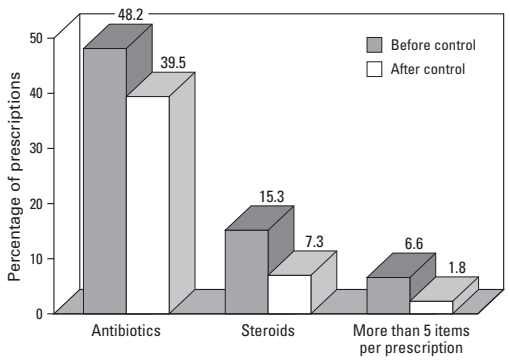
Promoting herbal medicines

Iran is rich in medicinal plants and in knowledge of how they can be used. But much needs to be done to promote their use. Herbal medicines have to be registered by the Department of Pharmaceutical Affairs, yet only 70 products have been through this process. Of these, 29 are currently on the market, and because they are not covered by health insurance policies they are not widely prescribed or used.

The first step to enhance the use of high quality herbal medicines was to set up the National Herbal Medicines Committee. Its nine members include the Director General of Pharmaceutical Affairs, two pharmacognosists, two physicians with particular knowledge of herbal medicines, a pharmacologist, a pharmaceutical expert, and specialists in medicinal plants and quality control of herbal medicines. One priority is to include approved herbal medicines in the official drugs list and to support their inclusion in the list of drugs covered by health insurance schemes. This will encourage more doctors to prescribe them. Education is another key to achieving optimal use of herbal medicines. A course on the subject is being developed for inclusion in the medical curricula. One drawback is that there are only 27 fully qualified pharmacognosists (with PhD degrees) in the country, although another 15 are being educated. The importance of public education on herbal medicines is also recognised.

There are very few herbal medicine production facilities, although another five factories are currently under construction. Other pharmaceutical factories are starting to include herbal medicines among their products and the Ministry of Health is actively promoting the development of new product lines.

The impact of the work of the Prescription Control Committee of Isfahan on the use of drugs



Drug pricing system on the agenda

Drug prices are low in Iran, particularly compared to neighbouring countries, because of the large Government subsidies. This has caused some problems. Any increase in the price of locally produced drugs must be approved by the country's highest financial authorities, which prevents price rises in line with inflation. Although the system favours consumers, it may affect the quality of drugs. And sometimes the non profitability of certain drugs causes shortages, as manufacturers have no incentive to produce them. The gross margins for producer, distributor and pharmacy are set at respectively 11%, 13% and 20% of the finished price of each drug. The price is calculated by a special committee consisting of representatives from pharmaceutical administration, industry and consumer organizations. There are many pressures from producers, distributors and pharmacists to remove drug subsidies or to increase the margins. The Board is reviewing the situation, in order to set margins which are more realistic in the current economic situation.

Boosting exports

Iran's 50 drug manufacturing plants are at a maximum of only 50% capacity. This has prompted the Government and industry to search for overseas markets, but so far with limited success. One obstacle may be the difficulty of competing with sophisticated multinational drug companies with their large marketing budgets. But as a result of very competitive prices offered by Iranian companies, it seems that new doors are opening and Iranian drug exports are taking off. Already more than 100 Iranian drugs have been registered in various Asian and African countries.

Future challenges

With the creation of the World Trade Organization, the prospect of Iran's membership of that Organization, and also the expansion of the global market economy, new challenges are emerging. The current drug situation in Iran is vulnerable to changes in the world and in the country. The pharmaceutical sector must be adapted to the new situation. The Pharmacy Board is therefore undertaking a comprehensive review of policies to identify how the pharmaceutical sector can continue to contribute to important national public health goals while at the same time be strengthened and fully competitive in a global market. At the same time the Iran Delegation at the World Health Assembly in May 1996 called for WHO "to report on the impact of the work of the World Trade Organization with respect to national drug policies and essential drugs and make recommendations for collaboration between the World Trade Organization and WHO..."[1]. We are hopeful that with the help of WHO expertise, the availability and accessibility of high quality and affordable drugs will be ensured in Iran and all countries. ❑

** Dr R. Dinarvand is Acting Deputy Minister for Pharmaceutical Affairs and Secretary, National Drug Policy-Making Board, Ministry of Health and Medical Education, 3rd Building, Fakhr Razi Street, Tehran 13145, Islamic Republic of Iran.*

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1. Included in resolution WHA49.14, Revised Drug Strategy

Oman develops NDP

OIL-RICH Oman may soon have a comprehensive national drug policy. The country's health services are free for all nationals and expatriates employed in the public sector. The burden of a rapidly growing population (growth rate of 3.4% a year) and the cost of running a health care system that is currently dependent on expatriates (87% of all doctors are foreigners) have caused the Government of Oman to examine how the health service can be made more efficient. With this aim, a national drug policy within the framework of a health policy, is being developed.

Many drug policy components are already functioning well but the varied training and experiential backgrounds of expatriate health workers have created a demand for drugs that is straining the health budget. Rational drug use will therefore be the main focus of the national drug policy. Already the medical school is revising its curriculum to include the concept of essential drugs and rational drug use. The Department of Clinical Pharmacology is planning to introduce training based on DAP's *Guide to Good Prescribing*.

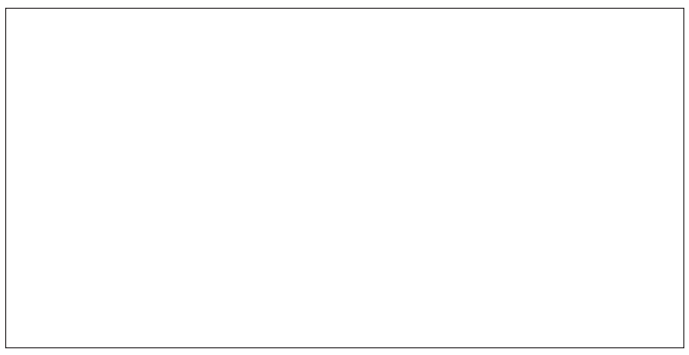
In August 1996 the Ministry of Health, with support from two WHO consultants, drafted a comprehensive national drug policy. This will be reviewed and finalised at a national workshop, and a comprehensive five-year plan of implementation will then be made. ❑

Eritrea: national workshop revises essential drugs list

AFRICA'S newest country, Eritrea, is forging ahead in improving the health of its people after 30 years of war. The national essential drugs list is considered fundamental to this process. An essential drugs list was developed and effectively used by the Eritrean National Front during the war of independence from Ethiopia, and was then used as the basis for a national list developed in 1993. But essential drugs lists need regular updating, so in late 1995 the Government widely circulated a questionnaire requesting proposals for amendments to the national list. Proposals for the addition to the list of 135 drug products and the deletion of 54 others were received.

In March 1996 a cross section of some 93 health professionals, veterinary and administrative personnel from both public and private sectors met in Asmara for three days. Although the principal aim was to review and debate the proposed amendments, and adopt a revised list, the gathering also provided a unique opportunity to discuss other important pharmaceutical issues. Discussions of the essential drugs concept, primary health care and national drug policy on the first day of the meeting provided a natural entry point to the subsequent more focused technical deliberations on the second and third days. Six multi-disciplinary working groups, reviewed the technical and scientific evidence (including cost/benefit) for the proposed amendments. Participants who had proposed amendments to the list had to be prepared to defend their proposals vigorously with adequate evidence. Working group recommendations were then reviewed and adopted by consensus in plenary sessions.

This process fostered an understanding of the need to rationalise the choice of drugs. It also created a sense of ownership and support for the final list, which increased in number from 289 to 362 drug products, and is applicable to both public and private sectors. The meeting was funded by BASICS, a USAID-sponsored organization, and facilitated by senior Ministry of Health officials and a DAP staff member. ❑



The new health centre at Serjka, 50 km from the Eritrean capital, Asmara. Peace is enabling the country to rebuild its health services

Photo: WHO/DAP/S. Muziki

NATIONAL DRUG POLICY

Ensuring value for money from pharmaceuticals in CCEE/NIS

Frans Stobbelaar*

The public and private pharmaceutical sectors in the Countries of Central and Eastern Europe and the New Independent States are in transition. Indications are that for large parts of the population drug availability has increased, but that for many people affordability has decreased. This article discusses common problem areas for pharmaceutical sector reform and recommendations for future strategies and policies.

Many problems now facing the health care system in the Countries of Central and Eastern Europe (CCEE) and the New Independent States (NIS) can be traced back to formerly highly centralised delivery systems, with their strong emphasis on quantity. Drug provision and distribution were similarly organized. The consequence was a poorly maintained and equipped, over-staffed and inadequately coordinated system, faced with serious structural problems. This, combined with an acute shortage of drugs, severe government budgetary constraints, lack of proper reimbursement and pricing mechanisms, and inadequate legislation and regulation, led to a crisis in the pharmaceutical supply system. Reform was critical, but in many cases created new problems that replaced the old.

Most CCEE/NIS turned to a market economy and privatised parts of the pharmaceutical sector. The process of change in the drug supply system in CCEE/NIS has typically followed certain stages (see Table), whose speed has depended on the national situation and on the influence of key people in the public and private sectors. The decision about whether or not to privatise was usually taken at an early stage in the transition period. This resulted in many "wild" cases of privatisation and forms of ownership in the drug supply system, which would be unacceptable in any Western country. Only a few countries included exceptions for the pharmaceutical sector in their legislation and very few kept the sector completely in state hands.

Hasty privatisation, combined with a lack of control and proper regulation, have led to chaotic and unmanageable development of the pharmaceutical sector. The results are high prices, a flood of imported drugs, and excessive margins and profits, to the detriment of accessibility and affordability. However, there are cases where the new market oriented (private) sector has saved a country from severe drug shortages. In some NIS especially, drug supply for community pharmacies was taken over by the private sector almost completely, due to governments' acute financial problems and the rigidity of the state owned sector.

It has become clear that a privatised drug supply system requires well functioning regulatory bodies which should be strengthened. In many countries the distribution system is not yet well established and has operational difficulties, basically due to its own, hospitals' and patients' lack of funds, and its small scale structure. Financial constraints and the limited possibilities for drug reimbursement lead to high out-of-pocket payments for patients, which seriously affect the availability and affordability of drugs for many people. The result is that although most governments have expressed their intention (and some have even legislated) to guarantee drug supply regardless of income and geographical location, the goals of accessibility, affordability and equity are frequently not met.

Photo: WHO/ILO

Drug production at a factory in Poland, one of the Countries of Central and Eastern Europe where the pharmaceutical sector is undergoing many changes

Key problem areas in pharmaceutical sector reform

The main problems are the inability/weakness of the public sector to manage the reform process properly; the complexity of that process; and the lack of the necessary tools to facilitate the task, exemplified in the following areas:

Priority setting by the state: often the state is more preoccupied with privatisation than health care financing and cost containment. This causes inequity, lower accessibility and affordability (high co-payments).

Lack of a national drug policy: some countries have not yet adopted a national drug policy – a coherent strategy for the pharmaceutical sector and a framework for the future for politicians, government officials and professionals. The lack of such a policy leads to ad hoc decision making and slows down the reform process.

Inadequate legislation and control: markets develop faster than public sector capacity and action. Legislative procedures are lengthy.

Drug financing and pricing mechanisms: some countries have a constitutional obligation to provide drugs free to large groups of the population. With increasing high priced imports, public drug expenditure is growing at rates far above western levels. Budgetary constraints are becoming tighter and the need for solutions is urgent.

Drug reimbursement systems, cost containment and need assessment: reimbursement systems and insurance funds may ease the burden of the government and the patient. However, they may be difficult to establish due to their complexity, and lack of legislation and funds. Need assessment is necessary, but rarely done properly and cost containment is generally a low priority issue.

Privatising distribution and restructuring the domestic industry: privatisation opens the way for a wide variety of ownership forms, but quality and professional standards are often inadequate. In order to establish a viable pharmaceutical manufacturing industry, large investments and transfer of knowledge are needed to achieve world standards (Good Manufacturing Practice). This takes time, good partners and funding, factors not always taken into account by countries.

Rapid market growth combined with irrational use of drugs: markets are growing very quickly as imports increase. At the same time overprescribing and polypharmacy cause high levels of irrational drug consumption.

Problematic drug donations: problems include distortion of the distribution system, providing unnecessary drugs or drugs with short expiry dates, and pushing new brands and unregistered drugs into a country.

Each of these key problem areas impacts on the main aim of public health policy: maximum accessibility to essential drugs.

Lessons learned

Governments need to improve their management of the drug supply system, strengthen health authorities and improve access to drugs (most of all the affordability of drugs for the entire population). These objectives can only be achieved if governments:

- Prioritise correctly. Public health objectives have a higher priority than private sector development. Equity and access are more important values than privatisation.
- Formulate and adopt a national drug policy. This should cover all elements of pharmaceutical sector reform. A national drug policy is a sector strategy, which avoids ad hoc decision making and acts as a catalyst and guideline during the process of change.
- Create negotiating platforms for relevant professional and public bodies. These groups need opportunities to discuss and advise on the development of the pharmaceutical sector and implementation of a national drug policy.
- Strengthen public sector bodies, such as departments of pharmacy, drug regulatory agencies and reimbursement funds. These have a leading legislative and regulatory role in the development of a market oriented drug supply system.
- Apply laws, regulations and conditions equally to private and publicly owned companies, regardless of ownership. Hidden subsidies hinder the sector's healthy development.
- Adjust systems to available funds. Public responsibility and solidarity require a focus on essential drugs (or positive lists); a drug reimbursement system with fair co-payment levels; cost containment incentives; the use of generic names; and the abolition of bureaucratic procedures that hinder availability and affordability.

cont'd on pg. 12

CCEE/NIS... cont'd from pg. 11

- Allow the new private sector the time and freedom necessary for it to develop an adequate distribution system, while establishing/maintaining the core legislative control essential to ensure safety and quality.
- Promote the rational use of drugs by prescribers and consumers. Decreasing high drug consumption is the most effective cost containment in the long run. Both supply and reimbursement systems should include rational drug use incentives.
- Learn from other countries, but don't simply copy. Each country has its own specific situation and peculiarities. Drug supply and regulation should be developed in accordance with the local situation.

Developments in CCEE/NIS show that unless adequate funding and just reimbursement mechanisms are in place, the social inequities caused by rapid privatisation of drug supply systems will continue to cause suffering for many. Governments, weakened themselves, are faced with the huge task of establishing appropriate sector regulation, health insurance schemes, cost containment and reimbursement systems, whilst under pressure from various groups in a new and fast changing environment. There can be no doubt that support from the international community will continue to be needed if many people in CCEE/NIS are to have access to an acceptable level of health care. ❑

Typical stages in drug supply transition in CCEE/NIS

Stage 1	Implicit introduction of private ownership	Introduction of private ownership in the drug supply system as part of general measures to encourage private initiatives within the framework of economic reforms, without subsequent adaptation of relevant legislation.
Stage 2	Emergence of private pharmacies	Private pharmacies emerge in addition to the existing state owned pharmacy system. These new pharmacies have many ownership forms (not necessarily limited to pharmacists), but most do not comply with accepted standards.
Stage 3	Decentralisation of state owned sector	Decentralisation of old structures is a prerequisite to privatisation of parts of the state-owned sector.
Stage 4	Privatisation of state owned sector	Privatisation takes place gradually depending on the available funds and the will to privatise. In many cases it is financed by profits from current sales. Some countries keep a strategic stake in the sector to guarantee supply and maintain some pharmacies or a wholesaler under state control.
Stage 5	Uncontrolled market expansion	Increased availability of imported drugs, rising prices, margins and profits, uncontrolled sale of drugs. Unacceptable and irresponsible behaviour, together with emerging social dissatisfaction (inequity) trigger the need for regulation.
Stage 6	Set up regulating authorities	Build supporting, controlling and regulating authorities. The initial focus on privatisation is replaced by investment in regulation and control structures. This process calls for key professionals and funds.
Stage 7	Sector regulation	Gradual regulation of the sector in terms of licensing, setting standards, limiting ownership forms and establishing new pharmacies, ensuring coverage in rural and remote areas, etc.

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LETTERS TO THE EDITOR

Screening Ayurvedic drugs

Editor,

In EDM-20 Dr Dinesh Chandra mentions the hazards of so-called Ayurvedic drugs which are contaminated with steroids. We have come across similar problems at the Ayurveda Research Centre, Seth G.S. Medical College & KEM Hospital, where we run an Adverse Reaction Monitoring Cell for Ayurvedic drugs. Over the last year we have screened 44 samples of Ayurvedic or homeopathic drugs prescribed for conditions such as bronchial asthma and rheumatoid arthritis, for the presence of prednisolone and dexamethasone on Thin Layer Chromatography. Ten samples were positive for prednisolone and 12 for dexamethasone.

Equally, if not more disturbing, were three referrals of serious lead poisoning, after use of an Ayurvedic drug. In each case illness occurred following ingestion of the same widely advertised, herbo-mineral, antidiabetic "Ayurvedic" formulation, available over-the-counter. This contained "Nag-bhasma", a lead preparation in Ayurvedic terminology. One patient had blood lead levels of 3.45 micro mol per litre (normal is 0-1 micro mol/l). When we received the complaints, the capsules were tested for lead levels by atomic absorption. There was 0.14% lead in the powder. At the drug's prescribed dose (one capsule twice a day), patients were ingesting 1.4 mg lead per day. The permissible level is 0.3 mg/day and a positive lead balance occurs at 0.6 mg/day. Patients were obviously going to develop lead poisoning with this drug.

It is evident that drugs belonging to any traditional system of medicine, particularly if they contain minerals, must have stringent quality control rules and should be regulated by drug legislation.

—Dr Urmila Thatte, Associate Professor (and Head, Ayurveda Research Centre), Dinesh Ucchil, Scientific Officer, Dr Sharadini Dahanukar, Professor and Head, Department of Pharmacology, Seth G.S. Medical College & King Edward VII Memorial Hospital, Parel, Bombay 400 012, India.

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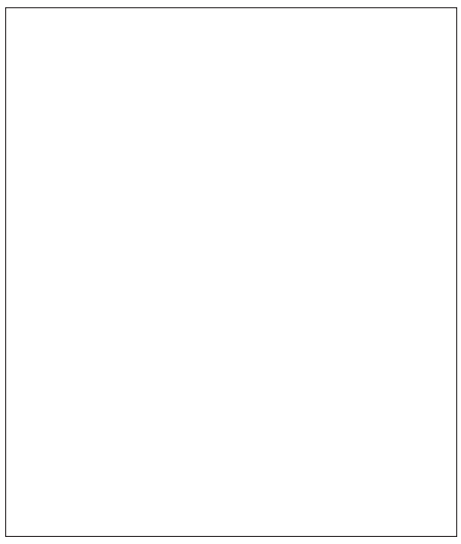
More on drug donations

Aid anarchy: getting to be a habit?

Editor,

In recent years an enormous quantity of drugs has been sent to the Mostar Region of former Yugoslavia from a variety of international sources in the guise of "humanitarian aid". However, the majority of such aid is useless for the following reasons:

- the drugs and other medical materials have already passed their expiry dates on arrival;
- the drugs and medical materials are completely inappropriate for the context;
- the drugs arrive in an unusable form, such as doctors' samples, half-used medicines, etc.;
- the drugs are totally mixed up in various boxes; in the difficult conditions of war and with a lack of health professionals, they cannot be sorted and so pass their expiry date before they can be used.



Zinc salve dated 1943. One of the drugs sent to Mostar

Photo: Médecins sans Frontières

At the moment 240 tons of drugs have to be destroyed in Mostar. But how? There is no incinerator. The organizations which funded these doubtful gifts could perhaps also fund their destruction.

How many tons of similar "aid" have also been sent to ex-Yugoslavia so that their donors can feel good? Such aid is no longer being sent according to needs but by volume and weight. Where do these stocks of out of date drugs come from? Some drugs sent to Mostar were more than 50 years old!! (see photo). Are they put to one side simply to make a grand gesture one day?

After such off the rails aid in Romania, Armenia and Bosnia who is going to be the next beneficiary of this largesse?

In Africa such aid often finds its way to the illegal market, where street vendors peddle doubtful Western medicines. What are the public health consequences of this? Surely there are enough problems for such countries in ensuring drug quality without adding this type of "humanitarian" anarchy.

To be effective, all aid must follow a careful analysis of needs, be properly coordinated and monitored in the field.

—Serge Barbereau, Pharmacist, Director General, Pharmaciens sans Frontières, 4 voie militaire des Gravanches, 63100 Clermont-Ferrand, France.

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Rethinking education for drug policy makers and regulators

Editor,

It has long been agreed that the regulation of drugs is necessary for public health. The present systems of regulation developed after the thalidomide disaster in 1959 had shown that drugs could seriously threaten health. It became clear that the introduction and promotion of drugs had to be controlled independently of the industry. Laws to do this were consequently introduced in most countries, and authorities set up in health ministries to administer and enforce them. In all countries the law and the regulators are therefore primarily concerned with what industry may and may not do. The main duty of drug regulators is to administer the law. They can reasonably argue, therefore, that they lack the resources to deal with other issues affecting the use of medicines which the law does not cover. Regulators are not *directly* concerned with how doctors, pharmacists and patients use medicines, or with what information they need to best use them. Yet these are areas in which not only regulators but legislators and administrators who set regulatory policies need to be educated.

Three aspects of drug regulation need to be improved. The ***first*** problem is that regulators have necessarily developed a close working relationship with their counterparts in pharmaceutical companies, but have little day-to-day contact with prescribers and virtually none with consumers. Yet what prescribers and patients do with medicines profoundly influences how effective and safe medicines are in practice. Regulators prefer to work through the industry, telling companies what they should tell prescribers and patients. But messages transmitted this way may be watered down and less effective than they should be. Two areas have been neglected: the choice of treatments by

cont'd on pg. 14 ➡

RATIONAL USE

Clinical guidelines in Scotland: a SIGN of the times

James Petrie*

THE purpose of clinical guidelines is to improve the quality of health care through the identification of good clinical practice on the basis of desired clinical outcomes. However, the process to develop clinical guidelines has many potential biases.

Scotland has taken an important initiative to reduce this bias and to increase the validity of its new national clinical guidelines. To this end a Scottish Intercollegiate Guidelines Network (SIGN) was established in 1993, which includes doctors, nurses, pharmacists, health service managers and professionals allied to medicine. SIGN methodology presents treatment recommendations together with a grading of the strength of the supporting clinical evidence.

SIGN is a close collaborative effort of the professional associations ("Colleges") and the Scottish Office Department of Health. The Network's creation coincided with the publication of a Government report[1], which advocated the development of national clinical guidelines – broad statements which describe an optimal level of care, in which current knowledge and clinical experience are balanced against possible constraints of staff and other resources. The report stressed that the national guidelines should be critically reviewed and modified to produce local protocols.

SIGN-sponsored national clinical guidelines put a strong focus on assessing the validity of the recommendations. The available evidence is reviewed and weighted by multidisciplinary groups and explicit links are made between the strength of the evidence and the strength of the recommendation. A wide group of professionals is involved in the process, which is important to create a sense of ownership of the guidelines, and ensure their successful adoption and use. There are also procedures for audit and review of the guidelines, which further increases their credibility and potential impact. It should also be stressed here that, although the relative cost-effectiveness of treatment alternatives is carefully considered, the SIGN guidelines are primarily intended to define "best practice", and not to contain cost. Several SIGN recommendations may actually result in higher health costs, for example in the case of disorders which are generally known to be under-diagnosed and under-treated in the community (e.g. diabetic retinopathy).

"Now what? It contains 17 amazing new miracle ingredients, but it doesn't do anything."

Consumers International

Developing national guidelines: the SIGN way

The guideline development group

The role of the development group is to prepare draft guidelines for debate at national workshops. For each national guideline the group suggests outcome indicators, a minimum data set, a draft quick reference guide and a patient specific reminder (for insertion in case notes for targeted groups of patients). In final form these national guidelines would be presented for local consideration and adaptation. Review dates are set at the time of publication.

The balance of disciplines within a guideline development group has considerable influence on the recommendations made and on successful implementation. SIGN requires the development groups to include representatives of key disciplines involved and, where possible, patients' representatives. Declarations of interest are made to the SIGN Secretariat by all group members. For example, information is requested on shareholdings or consultancies related to the drugs discussed and/or drug companies concerned, and any support received from a drug company to a member's employer.

Identifying evidence

In the United Kingdom and other countries, many guidelines are developed by expert groups but without formal literature reviews. This approach relies heavily on the group's knowledge of the literature and its members' clinical experience. However, clinicians' knowledge of the literature is often incomplete and experience may be biased, causing them to over- or underestimate a treatment's effectiveness. In SIGN-sponsored guidelines, evidence is identified by a systematic literature review. Details of search strategies and inclusion criteria employed to identify evidence are given[2]. Where possible, formal meta-analysis is quoted to synthesise the results across studies. All SIGN guidelines are fully referenced.

Developing recommendations

Guidelines normally contain recommendations based on different levels of evidence (Table 1). In using the SIGN guidelines as a starting point for developing local guidelines (for example in a hospital or district), local protocol developers need to be aware of the level of evidence on which the national guideline recommendation is based. SIGN uses the method of grading evidence and recommendations proposed by the US Agency for Health Care Policy and Research (Table 2). For example, a recommendation based on the results of at least one randomised controlled trial would be a Grade A recommendation based on Grade Ib evidence. A SIGN pilot booklet[3] provides guidance on development methods, content and format of SIGN-sponsored guidelines. The booklet also sets out criteria to assess the validity of guidelines.

Review mechanisms

Peer review and pilot testing prior to widespread dissemination and implementation are critical in guideline development. Appropriate mechanisms for reviewing draft guidelines need to be identified. SIGN has developed detailed criteria to appraise the development process, the content and the format of draft guidelines. The criteria cover:

- responsibility and support for guideline development
- membership of the development group
- evidence identification and synthesis
- assessing the strength of scientific evidence
- pre-testing and peer review of the draft guideline
- regular review process
- global assessment of validity of guideline development
- clinical applicability/flexibility
- clarity of the draft guideline
- likely costs and benefits

The availability of published appraisal criteria, such as those used by SIGN, will assist future developers, for example local groups, to produce evidence-based clinical guidelines themselves rather than having externally developed guidelines imposed on them by a particular advocacy group. By this emphasis on empowering local groups, SIGN is taking a lead in maximising the impact that guidelines can have on behaviour change and quality of care.

The first "new methodology" SIGN guidelines have already been published: *Prophylaxis of Venous*

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Table 1 **Levels of evidence**

Level	Type of evidence *(based on AHCPR* 1992)*
Ia	Evidence obtained from meta-analysis of randomised controlled trials
Ib	Evidence obtained from at least one randomised controlled trial
IIa	Evidence obtained from at least one well designed controlled study without randomisation
IIb	Evidence obtained from at least one other type of well designed quasi-experimental study
III	Evidence obtained from well designed non experimental descriptive studies, such as comparative studies, correlation studies and case control studies
IV	Evidence obtained from expert committee reports or opinions and/or clinical experience of respected authorities

** US Agency for Health Care Policy and Research*

SIGN... cont'd from pg. 13

Thromboembolism; Palliative Radiotherapy for Non Small Cell Lung Cancer; The Immediate Discharge Document; Prevention of Visual Impairment in Diabetes Mellitus; Acute Asthma: Hospital Treatment; Helicobacter Pylori: the Place of Eradication Therapy in Peptic Ulcer Disease; and *Obesity*. Working groups are preparing publications on: chest pain; proteinuria; haematuria; asthma; fractured neck of femur; antithrombotic therapy; stroke; and diabetes mellitus: other aspects. ❑

* *James Petrie is Chairman of SIGN and Professor of Clinical Pharmacology at the University of Aberdeen, Scotland, UK.*

For further information contact: Mrs Christina Pottinger, SIGN Administrative Support Centre, Royal College of Physicians, 9 Queen Street, Edinburgh EH2 1JQ, Scotland, UK. Tel: + 131 225 7324, fax: + 131 220 4393.

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2. Mulrow CD. Systematic review: rationale for systematic reviews. British Medical Journal 1994; 309: 597–9
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Table 2

Grading of recommendations

Grade	Recommendation *(based on AHCPR 1994)*
A *(Evidence levels Ia, Ib)*	Requires availability of at least one randomised controlled trial as part of the body of literature of overall good quality and consistency addressing the specific recommendation
B *(Evidence levels IIa, IIb, III)*	Requires availability of well conducted clinical studies but no randomised clinical trials on the topic of recommendation
C *(Evidence level IV)*	Requires evidence from expert committee reports or opinions and/or clinical experience of respected authorities. Indicates absence of directly applicable studies of good quality

Content and format of national guidelines

A fully developed clinical guideline is expected to comprise:

THE GUIDELINE REPORT containing
- a technical record of the guideline development process
- the literature review, with grading evidence
- the SIGN appraisal review report

THE CLINICAL GUIDELINE containing
- an executive summary
- a summary of the development process
- a summary of the literature review, with grading of evidence
- specific recommendations, graded according to the evidence base
- a quick reference guide

The quick reference guide
This summarises the recommended action, possibly in diagrammatic form. It is published as part of the clinical guideline itself and is a starting point for the local protocol which will be derived from the guideline and which will set out local practice. In some instances the quick reference guide may be adopted as the local protocol.

Editorial comment: the essential drugs concept is a global concept

This example from Scotland shows that the concept of essential drugs is globally valid. Of course the number of essential drugs on hospital formularies in Scotland is larger than on a list from developing countries (although it is interesting to note that the list of drugs reimbursed in the Australian Pharmaceutical Benefit Scheme is about the same length as the national list of essential drugs in Zimbabwe). Yet the principle of an evidence-based selection on the basis of efficacy, safety and cost-effectiveness is the same. Essential drugs are not second-rate drugs, they are not for poor countries, and not for rural areas only. The concept of essential drugs is just as valid in developed countries, in teaching hospitals, and in health insurance schemes. It is as valid for the treatment of cancer, cardiovascular diseases and metabolic disorders as it is for malaria, acute diarrhoea and pneumonia. ❑

Letters... cont'd from pg. 12

clinicians, health services and consumers, based on objective scientific comparisons between the possible alternatives; and educating and informing patients sufficiently to enable them to use medicines well. The first issue has begun to receive some attention. It is now accepted that the effectiveness of competing treatments must be compared. Health services and health insurance systems need such comparisons to ensure their efficiency and even their survival. But the present UK laws permit drug regulators to consider only comparative safety.

The ***second*** problem is that regulators expend more energy on licensing of new products than on reviewing the effectiveness, safety and use of marketed medicines. For financial reasons industry understandably wants new products registered without delay. As many regulatory agencies are largely funded by fees from industry, they try to work quickly. Once a drug is licensed their main concern is safety in practice; efficacy has been proved to their satisfaction and receives no further attention – unless the company asks for an extension of the licence to a new indication.

Regulatory agencies have developed no mechanism for routinely reviewing scientific knowledge about a drug whenever a new study is published which may affect its use, except when it concerns a serious suspected adverse reaction. Product licence renewals are often a bureaucratic formality, without any scientific review. While the pharmaceutical industry needs a stable regulatory environment in order to plan ahead, it should nevertheless promptly adapt its marketing and information policies to new knowledge. Regulators have a duty to ensure that this happens. While most authorities are not allowed to consider comparative efficacy in deciding whether to grant a product licence, this should not prevent them from amending the indications, dosage, contraindications and warnings of a licensed drug, even if the relevant new data concern a different, perhaps competing, drug.

Medicines can do serious harm as well as good, which is why drug regulation came into being. A ***third*** problem is that far less regulatory resources are used to detect, investigate and learn from harmful drug effects than are devoted to checking data on drug efficacy and quality. This is partly because drug regulatory authorities are not adequately funded or organized to undertake or sponsor the necessary research. This has led to a large imbalance in resources between those available for therapeutic research, in industry and the public sector, and those for work on harmful effects. International and national efforts must be made to reduce this imbalance.

—Dr Andrew Herxheimer, Consultant, Cochrane Centre, Summer Town Pavilion, Middle Way, Oxford OX2 7LG, UK.

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Researching medicinal plants in Turkey

Editor,

There are more than 3,000 endemic plant species which have been used for centuries in Turkish folk medicine because of their curative properties. In more recent years interest in isolating their active ingredients in order to develop drugs from these natural sources, has grown rapidly.

The main approach in studying and evaluating such medicinal plants is to examine their traditional uses. A plant's effectiveness in curing particular diseases and its pharmacological actions lead us to investigate and identify its chemical compounds. As well as being effective, these compounds must be safe for internal consumption or external application. For example, some plants are toxic for oral use, while others can be toxic in long-term therapy but non toxic on a short-term basis. Pharmacological and chemical analysis can be used to assess the safety of a given traditional remedy. Medicinal plants, either in the form of crude drugs or their isolated medicinally active substances, will be important among the treatment choices available to physicians.

The Herbal Medicine Research and Development Centre has been established in the Cerrahpasa Medical Faculty of the University of Istanbul. It is responsible for providing research facilities and training in medicinal botany, the chemistry of natural products, and their biological and pharmacological evaluation.

We look forward to establishing links and cooperating with institutes which share our aims, and which are willing to carry out joint studies on endemic plant species with the scientists here.

—Dr Gülsal Kavalali, Associate Professor in Pharmacology, Cerrahpasa Faculty of Medicine, Pharmacology Department, 34303 Cerrahpasa, Istanbul, Turkey.

Further information can be obtained from: c/o Dr Gülsal Kavalali, Director, Herbal Medicine Research and Development Centre, Cerrahpasa Tip Fakültesi, Temel Bilimler Binasi Bodrum Kat 1, 34303 Cerrahpasa, Istanbul, Turkey.

Writing for the Monitor...

Readers interested in submitting articles to the *Monitor* often write to ask for editorial guidelines.

We aim to describe national and international initiatives related to drug policy and the rational use of drugs – both development and implementation – especially work from which others can learn. We are particularly interested in publishing reports on how countries are monitoring the implementation of policies, what problems are encountered and how they are overcome; or any strategies that are truly innovative.

EDM articles should be as brief as possible, normally a maximum of 1,500 words. News items should be approximately 400 and letters 200 words. Limitations of editorial space mean that we may have to condense some of the information or just give a summary overview of principal activities. In the case of full length features, authors are sent the edited text for approval. We reserve the right to publish news items and letters to the editor without reference back to authors. The full name and a description/title of the post(s) held by the author(s) should be given. Photographs or other illustrations to accompany the text are most welcome, with an exact description of what they show.

We can make no commitment in advance regarding publication, since a decision depends on both the article content and available space in a given issue. However, we hope this is not a deterrent, as we are always pleased to receive readers' contributions.

DRUG INFORMATION

Drug information in Nepal: bringing professionals together

IN August 1993, in collaboration with the Action Programme on Essential Drugs, the Rational Pharmaceutical Management (RPM)* Project completed an assessment of Nepal's pharmaceutical sector. Subsequently, in March 1994, RPM along with other USAID projects, local NGOs and the Ministry of Health's Logistics Management Division, launched a major programme to upgrade the procurement and distribution system for family planning, drug and medical supplies. In July of the same year an RPM team visited Nepal to assess the feasibility of complementing the work in logistics with work in the areas of drug information and rational use.

The most important finding of the feasibility assessment was that a number of groups, including the Ministry of Health's Department of Drug Administration, the national university's Institute of Medicine and at least three NGOs, were already active in these areas. It was also found, however, that these organizations were working largely in isolation from one another, which limited what each was able to accomplish and their collective impact. RPM's role has been to: mediate the coming together of these groups; provide resources in the form of technical assistance, equipment and technical references; and help implement focal activities in drug information and rational use.

Drug Information Network

The availability of up-to-date and unbiased scientific information on drugs is a fundamental requirement for all communication and training activities. Conventionally, such information is provided through a centre that is equipped with appropriate reference materials and staff trained to use them. But on considering basic questions, such as: What is the demand for this sort of information? Who needs or wants it? Where do these consumers seek assistance now? Nepal has determined that the best approach would not be one large information centre, but rather a network of smaller sites, each equipped and staffed to respond to an identifiable group of users. Five sites were identified:

- The Department of Drug Administration itself, the natural constituencies of which are Ministry of Health health care providers, and parties from the commercial sector interested in drug registration and licensing information;
- The Tribhuvan University (TU) Institute of Medicine, which has great potential to influence medical opinion leaders, particularly hospital-based physicians;
- The Resource Centre for Primary Health Care, an NGO that is active with consumers and has a special interest in primary health care and community outreach;
- The Nepal Chemists and Druggists Association, the representative association of drug retailers;
- The Nepal Health Research Council.

Photo: WHO/L. Taylor/SCF

A doctor examines a young patient in Nepal, where increased collaboration is improving the effectiveness of drug information and rational use initiatives

A key point is that these organizations were already up and running. That is, they have not been created by RPM and are not financially dependent on RPM. In addition, each one already produced a bulletin or newsletter, thus giving the network a number of active channels of communication to its various constituencies.

Once the network members were identified, the next steps were to provide equipment and staff training. RPM carried out a survey to determine equipment and reference material needs. Based on this, each site was provided, as required, with a computer, printer, fax machine, telephone answering machine, selected reference books and the US Pharmacopeia Drug Information Database on CD-ROM. One staff member from each site received training in drug information centre operations, through a study tour to appropriate organizations in Malaysia and the United States.

On 23 September 1996, following a year and a half of preparation, the Drug Information Network of Nepal was launched by Minister of Health, Mr Arjung Narasingha. The Network provides a question and answering service (by 'phone, mail or to personal callers), and proactively disseminates scientifically validated drug information. Each site has a particular technical focus (see Box) and works independently. But where necessary members can refer queries to each other.

Rational drug use strategy

In parallel with the drug information developments, RPM has also collaborated with the Department of Drug Administration to develop a practical strategy for promoting rational drug use in the Ministry of Health's network of almost 3,000 health posts and sub-health posts. This activity is also based on collaboration with a number of different groups, which include:

- The Department of Drug Administration, which has normative responsibility for drug product selection and use;
- Technical committees of senior experts, coordinated by the Department of Drug Administration, and responsible for maintaining Nepal's Essential Drugs List and determining standard norms of treatment for health problems;
- The Institute of Medicine's Health Learning Materials Centre, which has expertise in the development of printed materials for health worker training and consumer outreach;
- The Nepal chapter of the International Network for the Rational Use of Drugs (INRUD), which has special expertise in operations research and training.

Priority has been given to two interrelated activities. One is the revision and publication of the Standard Drug Treatment Schedule for primary health care workers. The other is the design and testing of a strategy for improving drug use that is based on initial training of care providers followed by supervision, monitoring and feedback of prescribing practices. The initial focus of the strategy will be three health problems: diarrhoeal disease, acute respiratory infections (ARI) and diseases of the skin.

The plan is to coordinate publication of the treatment schedule with development of training and supervisory materials and testing the strategy in at least two districts over an 18-month period. This test will be evaluated by comparing changes in prescribing practices between test and control districts. It is hoped that this effort will eventually result in the development of a practical approach to promoting rational drug use that is suitable for replication throughout the public sector.

Putting it all together

Work in Nepal demonstrates the importance of collaboration for making progress in the technically complex endeavours of disseminating drug information and promoting rational use. It is simply not possible to find all of the expertise that is required in one place. Under the leadership of the Department of Drug Administration, no fewer than six groups from the academic and NGO sectors have been brought together to work on a focused set of activities. The individual groups and their activities are mutually reinforcing. The first stream of work has resulted in the creation of the Drug Information Network of Nepal. As work goes forward on the second stream, the Network will be an important technical resource for the effort to promote rational drug use. ❑

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

* The Rational Pharmaceutical Management (RPM) Project is a USAID-funded project based on two cooperative agreements, one with Management Sciences for Health and the other with the US Pharmacopeial Convention.

Technical focus of the Drug Information Network's sites

Site Service process	Department of Drug Administration	Drug Information Unit, TU Teaching Hospital	Nepal Health Research Council	Nepal Chemists and Druggists Association	Resource Centre for Primary Health Care
Primary audience	Ministry officials, drug manufacturers, drug traders, health professionals	Prescribing doctors, pharmacists, nurses, medical students	Health researchers	Chemists, patients, care-givers	Consumers, journalists, community leaders
Secondary audience	Clinicians, paramedics	Patients, care-givers	Patients, care-givers, community leaders	Medical professionals, manufacturers, nursing homes	Researchers, primary health workers, NGOs, students
Information provided	Mainly regulatory and legal issues; product availability	Drug facts and therapeutics-related information	Research – and drug-related information	Mainly information on availability, brand names, storage, prices. Patient counselling	Mainly consumer-related drug and health information. Provision of reference materials

NETSCAN

http://www.who.ch — information at your fingertips

WHO serves the information needs of the many professionals who seek instant electronic access to the latest data and statistics. The WHO homepage on the World-Wide-Web makes it easy for Internet users to retrieve up-to-date, health related data on a range of topics. Users can find descriptions of the major programmes coordinated by WHO, global and country specific health statistics, country profiles, WHO events attracting media attention, data on individual diseases, and alerts to outbreaks of disease. Information about important WHO publications, press communications and reference to more than 60,000 items in the WHO library database are also instantly available, as are the full texts of frequently referenced publications.

WHO's homepage enables the user to retrieve information about the regional offices, country activities, WHO collaborating centres and depository libraries where complete collections of WHO publications are maintained. For more specialised information within the UN system, links are provided to the homepages of the WHO Regional Office for Europe, the Pan American Health Organization, the International Agency for Research on Cancer and other UN agencies. ❑

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FDA increases information on the 'Net

The US Food and Drug Administration plans to make many public documents available electronically in the coming months. The agency will soon add links to:

- approval letters;
- approved drug labelling;
- a data standards manual;
- drug quality reporting systems forms;
- a guide on inactive ingredients;
- drug safety reports from the MedWatch programme;
- information on orphan drug products;
- a list of Phase IV post-approval clinical trials.

By accessing the section of the site on human drugs, Internet users can already obtain information on AIDS clinical trials, approved drug products with therapeutic equivalence evaluations, a list of drug approvals since February 1991, a directory of national drug codes, patent term extensions and consumer information on over-the-counter drugs.

A separate "FDA News" page contains the Agency's most recent announcements, discussion and background papers, and schedules of FDA Advisory Committee meetings.

Access the FDA at: http://www.fda.gov ❑

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Guide to Good Prescribing now online

The *Guide to Good Prescribing* (see EDM-20) is now available online. It can be accessed either through DAP's homepage (see right) or through the WHO Collaborating Centre for Pharmacotherapy Teaching and Training at the University of Groningen, where the teaching methodology was originally developed: http://www.med.rug.nl/pharma/who-cc/homepage.htm

The web site includes three sections:

- Complete Guide: includes all illustrations in the hard copy;
- Text only Guide: for low-bandwidth access;
- Archives: downloadable files in different formats for off-line use.

Get the Guide by e-mail

For those whose internet access is limited to e-mail, a file server is functional. To obtain the Guide in this way send an e-mail message to: in-depth@med.rug.nl, with one of the following messages appearing EXACTLY as the SUBJECT of your e-mail:

To receive a copy of the Guide to Good Prescribing in Word 6.x for Windows format: SEND GGPWIN.ZIP

To receive a copy in Word 5.x for Apple MacIntosh format: SEND GGPMAC.ZIP

As a reply you will receive an e-mail with one of the following documents sent as an attachment: GGPWIN.ZIP (100 Kilobytes) or GGPMAC.ZIP (90 Kilobytes). After extracting the mail attachment, you need to decompress the zipped file by using PkZIP 2.04g or a compatible software program.

Download the Guide from the Web

To download the Guide in one of the following formats for off-line reading: HTML (for Netscape Navigator and MS Internet Explorer), Word 6.x for Windows, Word 5.x for Apple MacIntosh: www.med.rug.nl/pharma/ggp_text/download.htm ❑

Photo: University of Groningen

Dr Yunus Kocabasoglu of the University of Groningen's Department of Clinical Pharmacology setting up the Guide to Good Prescribing web site

DAP's homepage

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

The titles of selected WHO, DAP and other pharmaceutical publications are available on the homepage. In addition, text from selected DAP publications can be viewed and downloaded. For example, feature articles from the English version of the *Monitor* are available from issue number 19 onwards, and users can also print out the *Guidelines for Drug Donations* and *Guide to Good Prescribing*.

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

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Weekly Epidemiological Record

WHO's *Weekly Epidemiological Record* provides official information on diseases subject to the International Health Regulations (cholera, plague and yellow fever), other communicable and non communicable diseases, and public health problems. Published every Friday in a bilingual English/French edition, WER is available on the Internet at the following address: http://www.who.ch/wer/wer_home.htm

In addition, an automatic service is available for receiving a weekly notification of the contents of the WER and short epidemiological bulletins. To subscribe send an e-mail message to: majordomo@who.ch

The subject field should be left blank and the body of the message should contain **only** the line: subscribe wer-reh

Subscribers will automatically be sent a copy of the table of contents of the WER each week, together with other items of interest. ❑

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BUKO Pharma-Kampagne

Pharma-Brief, the newsletter of the German consumer group, BUKO Pharma-Kampagne can now be accessed through the Internet. It is part of the "Development Policy Online Service", which provides a wide range of information and references to other sources of information. To access *Pharma-Brief* connect to: http://users.aol.com/suednetz/epo/epo.htm ❑

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At ease with e-mail

Computer-based communications – through electronic mail (e-mail), bulletin board systems, computer conferencing and networking and on-line databases – offer NGOs, particularly in developing countries, a modern, effective and affordable communications toolkit with which to share information, network, conduct research, and support advocacy work and campaigns on development issues.

At Ease With E-mail: A Handbook on using Electronic Mail for NGOs in Developing Countries, prepared by the United Nations Non-governmental Liaison Service and the Friedrich Ebert Foundation (New York), is for beginners. Step-by-step, and in question and answer form, the publication introduces the rapidly developing field of communications technology by explaining basic terms and concepts, offering advice and contacts, listing existing computer communications networks and local e-mail service providers, and suggesting ways to benefit from these communications tools. It also contains a directory of low cost country networks.

Available, free of charge, from: United Nations Non-Governmental Liaison Service. E-mail:ngls@igc.apc.org **or** ngls@nywork2.undp.org **or** the Friedrich Ebert Foundation, New York. E-mail: fesny@igc.apc.org **or** fesny@undp.org ❑

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MEETINGS & COURSES

Pharmacoepidemiology Conference

The 13th International Conference on Pharmacoepidemiology will be held from 24–27 August 1997, in Florida, USA. Sponsored by the International Society for Pharmacoepidemiology, the conference will focus on global public health issues, and will include a session on drug use in developing countries. ❑

For further information contact: Dr Stanley A. Edlavitch, ISPE Office, University of Kansas Medical Center, Department of Preventive Medicine, Robinson 4004, 3901 Rainbow Blvd., Kansas City, Kansas 66160-7313, USA. Tel: +913 588 2790, fax: +913 588 2791, e-mail: ISPE@KUMC.EDU

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Improving the Use of Medicines

An International Conference on Improving the Use of Medicines will be held in Chiang Mai, Thailand, from 1–4 April 1997. The conference will bring together individuals involved in investigating and implementing programmes to improve the use of medicines, with an emphasis on developing and recently industrialised countries. Participants will examine and review the available scientific evidence about interventions to improve medication use; identify effective strategies and their implications for policy and programmes; and establish directions for future research.

The conference will be of particular interest to pharmaceutical researchers, policy makers, health programme managers, staff from international agencies and donors, international pharmaceutical consultants, pharmaceutical industry representatives and consumer organizations. ❑

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

Effective drug management

The next course on "Effective Drug Management and Rational Drug Use" (see EDM-21), is to be held from 12 May to 11 July 1997 at The Robert Gordon University, Aberdeeen, Scotland. The course is suitable for health professionals, especially pharmacists, who are involved in the management of drug supply in the public sector or in nongovernmental organizations. ❑

For further information contact: The Robert Gordon University, School of Pharmacy, Schoolhill, Aberdeen AB9 1FR, Scotland, UK. Fax: +44 1224 626559, e-mail: p.spivey@rgu.ac.uk

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Training course on drug management in Africa

The next specialised training course on drug management for the public sector in Africa (see p. 2) will be held in Cotonou, Benin, in autumn 1997. ❑

For further information contact: Facultés de Pharmacie, 15 avenue Charles Flahaut, 34060 Montpellier Cedex 2, France.

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Groningen summer course

The next annual pharmacotherapy teaching summer course at the University of Groningen will be held from 21–29 August 1997. Participants – mainly university pharmacology teachers – are exposed to training on the principles of rational pharmacotherapeutics and then in the second week teach the same course to a group of medical students. ❑

For further information contact: Department of Clinical Pharmacology, University of Groningen, Bloemsingel 1, 9713 BZ Groningen, the Netherlands. Fax: +31 50 3632812; e-mail: summer.course.pharmaco@med.rug.nl

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Promoting rational drug use

The next INRUD/DAP course on Promoting Rational Drug Use will be held in Tanzania in September 1997. Topics will include identifying drug use problems, developing and evaluating interventions, and the development of public and prescriber educational materials and campaigns. Course work will be highly participatory and practically oriented. ❑

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

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Second course on drug policy issues

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

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

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Medical anthropology in Amsterdam

The University of Amsterdam is offering an advanced masters course in applied medical anthropology for social scientists, physicians and other health care professionals, who are confronted with difficulties related to the socio-cultural context of their work. Applicants should have a masters degree in any of the social sciences or in the fields of medicine, public health, pharmacology or a paramedical science, although other professional qualifications may be considered.

Starting on 1 September 1997, the course is 12 months full-time. Alternatively four modules are open to those who wish to study part-time: Gender, Reproductive Health and Fertility; Chronic Illness: Perceptions and Practices; Social, Cultural and Historical Dimensions of Infectious Disease; and Culture, Psychology and Psychiatry. ❑

For further information contact: Dr Ria Reis, University of Amsterdam, Faculty of Social Sciences, Medical Anthropology Unit, AMMA Programmme, Oudezijds Achterburgwal 185, 1012 DK Amsterdam, the Netherlands. Tel: +31 20 525 2670, fax: +31 20 525 3010, e-mail: amma@pscw.uva.nl

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PUBLISHED LATELY

Important

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

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

Handbook of Drugs for Tropical Parasitic Infections, 2nd ed., Y.A. Abdi, L.L. Gustafsson, O. Ericsson, U. Hellgren, 1995, 181 p.

This revised and updated edition of *Handbook of Drugs for Tropical Parasitic Infections* provides well-evaluated information on the pharmacological properties and therapeutic use of the major drugs used to combat human parasitic infections in the tropics. For each of the 38 drugs covered, data and information are presented on: chemical structure; physical properties; pharmacology and mechanism of action; pharmacokinetics; clinical trials; use in pregnancy and lactation; side effects; contraindications and precautions; dosage; preparations; and references.

The publication is largely designed for physicians, pharmacists, health workers, medical students and nurses in developing countries. It will also be useful for clinicians and medical students in non endemic areas who need information on drugs that is not normally included in their local therapeutic guidelines.

Available from: Taylor and Francis, Rankine Road, Basingstoke, Hampshire, RG24 8PR, UK. Price: £18.50.

Vaccination Against Pregnancy: Miracle or Menace, J. Richter, 1996, 182 p.

A totally new class of birth control methods is currently under development: immuno-contraceptives, or antifertility 'vaccines'. Why and how are immunological birth control methods being developed? What will they mean for the major 'target' group – marginalised women in developed and developing countries? Judith Richter looks at the ongoing research and assesses the risks and benefits from a user-centred perspective. She questions the ethics of developing new birth control methods which she argues carry potentially serious risks and no advantages over existing methods. The author describes a global coalition now calling for a stop to this research and assesses the likelihood of influencing the research agenda by describing the campaign's successes to date.

Available from: Zed Books, 7 Cynthia Street, London N1 9JF, UK. Price: £11.95 paperback, and £37.50 hardback.

Unpacking the GATT: a Step by Step Guide to the Uruguay Round, P. Evans, Consumers International, 1994, 108 p.

Trade is linking countries, economies and people in ways never seen before. More countries are joining the scramble for international markets, more workers are involved in the export trade and more economies are having to adapt to a world without frontiers.

International trade is expected to grow dramatically thanks to the signing in April 1994 of the latest world trade agreement, the Uruguay Round of the General Agreement on Tariffs and Trade (GATT), and the setting up of the World Trade Organization.

This book provides a clear, concise and thorough guide through the complex maze of new rules for global trade, while also examining their crucial implications for consumers.

Available from: Consumers International, 24 Highbury Crescent, London N5 1RX, UK. Price: US$12.95 + 20% for packing/postage.

The Management of Acute Respiratory Infections in Children. Practical Guidelines for Outpatient Care, WHO, 1995, 75 p.

Addressed to health staff working in first level facilities, this book is a guide to the management of acute respiratory infections in children under five years of age. It offers detailed instructions on recognition of the symptoms of respiratory infections and selection of appropriate treatment, including referral to hospital, antibiotic treatment and care at home.

The first part of the publication deals with the management of pneumonia, wheezing, coughs and colds, while the second part covers the management of ear infections and sore throats. Also included are guidelines for the management of measles, pertussis and diphtheria in the under-fives, and for their referral to hospital, together with instructions on how to use rapid acting bronchodilators.

Available from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.15, US$13.50, and in developing countries Sw.fr.10.50.

Stability of Essential Drugs in Tropical Climates: Zimbabwe, WHO/DAP/94.16, 1996, 77 p.

The latest in DAP's Research Series describes an 18-month longitudinal study which assessed the quality of 13 essential drugs commonly used in Zimbabwe. Researchers compared the quality of drugs at selected health centres and district hospitals with the initial quality measured in the central medical stores. They also determined whether substandard quality is associated with specific factors – age, duration of storage and conditions at facility level, transport method or drug manufacturer.

Selected drugs satisfied two criteria: known or suspected quality or stability problems under adverse climatic conditions; and relevance for public health care (drugs on the national essential drugs list with a high turnover in the public sector drug distribution system). The main measure of drug quality was an assay value for a drug's active ingredient expressed as a percentage of the stated content. Nine of the 13 drugs maintained satisfactory quality up to the endpoint in the public sector health care system.

In addition to the study design, methodology and results, the report offers practical recommendations for developing an effective quality assurance system.

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

Essential Drugs Monitor

A Guide to Eliminating Leprosy as a Public Health Problem. A Pocket Edition, WHO, WHO/LEP/95.1, 1995, 102 p.

Even though leprosy continues to afflict a large number of people, it is now possible to eliminate it as a public health problem. This is largely the result of 10 years' intensive use of treatment based on a combination of antileprosy drugs known as multidrug therapy (MDT). The purpose of this pocket guide is to enable every health worker in endemic countries to play an effective role in eradicating leprosy. The *Guide* gives a clear picture of what needs to be done to implement MDT. The publication is in four sections: facts about the disease; the elimination strategy; diagnosis; and classification of leprosy. Only the most important concepts are discussed, and details of action to be taken, including technical steps, are provided.

Although useful for health workers at all levels, the *Guide* is targeted mainly at those who have major responsibility for organizing and implementing leprosy work in the field. The publication can be used in training courses and as self-learning material.

Available, free of charge, in English and French, from: World Health Organization, Action Programme for the Elimination of Leprosy, 1211 Geneva 27, Switzerland.

Guidelines for Preparing Core Clinical-Safety Information on Drugs, Council for International Organizations of Medical Sciences, 1995, 69 p.

The absence of internationally agreed standards for the format and content of information on pharmaceutical products for prescribers and other health care professionals gives rise to discrepancies and inconsistencies between countries and between manufacturers. A Working Group of the Council for International Organizations of Medical Sciences was established to suggest ways to improve the situation. This publication reports on the Group's proposals for international harmonisation of safety aspects of drug data sheets. As well as setting out general principles, the publication covers specific aspects of the "what, when, how, why, where and who" of producing core safety information.

Available, free of charge, in English and French, from: Council for International Organizations of Medical Sciences, c/o World Health Organization, 1211 Geneva 27, Switzerland. Price: Sw.fr.15/US$13.50, and in developing countries Sw.fr.10.50.

Medical Stores 'C-List' Catalogue, 1995, Government Medical Stores and the Zimbabwe Essential Drugs Action Programme, Ministry of Health and Child Welfare, Republic of Zimbabwe, 1995, 38 p.

In EDM-21 we announced publication of *Selecting Medical Supplies for Basic Health Care*, ECHO's model list of essential medical supplies. Another such list containing 140 non drug products and medical supplies for primary level care has been published by Zimbabwe's Essential Drugs Action Programme (ZEDAP). Each item has been classified according to level of need. The list includes items such as needles, syringes, catheters and tubes, dressings, sutures, stationery, disinfectants, dispensing sundries, raw materials and laboratory equipment. The catalogue also contains approximately 80 drugs for use at the "C" level of care.

As with all ZEDAP modules this catalogue was prepared in collaboration with its users – health workers from the primary health care level, and provides many useful and easy to read hints and guidelines.

A catalogue is also available for health workers at all other levels. *Catalogue 1995 Medical Stores* includes a list of essential medical devices (non drug items) for use at central hospitals down to rural health clinics, together with valuable hints and guidelines.

***Medical Stores C-List Catalogue** and **Catalogue 1995 Medical Stores** are available, free of charge, from: ZEDAP, Ministry of Health and Child Welfare, P.O.Box CY 924, Causeway, Harare, Zimbabwe.*

Catalogue of Health Indicators, WHO/HST/SCI/96.8, 117 p.

Indicators are markers of health status, service performance or resource availability, defined to enable the monitoring of objectives, targets and performance. This *Catalogue* provides a brief description of a selection of health indicators currently recommended by WHO's technical programmes for use in managing national health programmes and services. Of the 57 indicators, 22 relate to infants and children, 10 are specific to women's health and the rest concern general population issues, including drug quality.

The document is intended as a reference for national public health service administrators, and health programme and service managers involved in health monitoring. It will be updated periodically as new indicators are tested and approved.

Available, free of charge, from: World Health Organization, Division of Strengthening Country Health Information, Unit of Strengthening Country Health Information, 1211 Geneva 27, Switzerland.

Health Information Centres in Europe. What is Their Status? How Should They Develop? M. Bonati, G.Tognoni (eds.), 1995, 112 p.

When economic interests are an increasing driving force in the health field and information is frequently redundant, contradictory or full of jargon, the development of independent centres of information answering questions on drug use and disease prevention is vital. This is the central argument of the publication which consists of papers presented at an international workshop on Health Information Centres in Europe, held in Bergamo, Italy, in June 1994.

The workshop assessed the characteristics, functions, purposes and achievements of European information centres; explored the opportunities and criteria for networking; and identified neglected areas which need to be developed at European and national levels. Speakers from developed and developing countries presented papers grouped under four headings: "Model Experiences from the Drug Field; Disease/Problem-oriented Information; Health Information Providers and Consumers; and Model Initiatives from Developing Countries.

The workshop concluded by looking to the future and the challenge of involving consumers as full partners in the planning and implementation of health care programmes.

Available, free of charge, from: The "Mario Negri" Institute for Pharmacological Research, Via Eritrea 62, 20157 Milan, Italy.

Facing the Challenges of HIV, AIDS, STDs: A Gender-based Response, Royal Tropical Institute, the Netherlands, Southern Africa AIDS Information Dissemination Service and WHO/Global Programme on AIDS, 1995, 52 p.

A gender-based response to the HIV/AIDS epidemic and sexually transmitted diseases (STDs) focuses on how the different social expectations, roles, status and economic power of men and women affect and are affected by the epidemic. Central to such a response is an analysis of gender stereotypes and an exploration of ways to reduce inequalities between women and men. This publication provides policy makers, planners and those implementing programmes with information and ideas to help them incorporate a gender-based approach to HIV/AIDS and STDs.

Personal testimonies and brief descriptions of programmes and interventions personalise the text, show the impact of gender inequality on female and male risk and coping, and provide examples of effective responses. A useful checklist is provided for assessing the gender-based focus of existing or planned programmes and interventions.

Available, free of charge, in English and French, from: Royal Tropical Institute, Information, Library and Documentation, Mauritskade 63, 1092 AD Amsterdam, the Netherlands.

International Experience in Rational Use of Drugs, Vol.2, R.R. Chaudhury (ed.), 1996, 163 p.

The second volume of *International Experience in Rational Use of Drugs* has been published at a time when the cost of health services is rising, and needless expenditure on irrational, unnecessary medicines consumes an unacceptably high percentage of countries' total spending on health care. However, there are examples where innovative interventions aimed at rational use of drugs have begun to make an impact. This series aims to disseminate these experiences as widely as possible, so that health service managers can assess their relevance to their own situations.

The first chapter looks at drug use in broad terms, pinpointing the faults in current systems, analysing the causes and suggesting remedies. This is followed a DAP contribution, which discusses measures to curb irrational use of drugs caused by self prescribing. A description of Zimbabwe's successful training programme for doctors and health workers in rational use of drugs provides a useful model for others. The publication also includes country studies of Thailand and Myanmar, describes the implementation of a rational drug use programme in the Indian State of Delhi, and concludes with an insight into the rational use of herbal medicines at the primary health care level in Thailand.

Available, free of charge, from R.R. Chaudhury, UNESCO Chair, College of Public Health, Chulalongkorn University, Institute Building 3, Phyathai Road, Bangkok 10330, Thailand.

Emergency Relief Items. Vol 2, September 1996, UNDP, 233 p.

There has been a worldwide increase in the number and the seriousness of emergencies. The management of major emergencies requires multisectorial cooperation and preparedness at the local, national, regional and international levels.

This catalogue of recommended relief items resulted from intensive collaborative interagency efforts led technically by WHO. It aims to promote the standardisation of medical supplies and equipment, and is based on experience gathered over the years by the major disaster relief organizations. The catalogue – which covers medical supplies and equipment, and selected essential drugs – provides complete basic specifications for all selected items together with information on shipping weight/volume. A United Nations Common Coding System (UNCCS) number has been allocated to each product to facilitate exchange of information. The publication also contains the interagency guidelines for drug donations published by WHO in May l996.

The catalogue will provide very useful guidance to donor and recipient countries. It will also be a valuable practical tool for procurement officials in the UN system, NGOs and development agencies involved in the acquisition of emergency relief items.

A database of items for the relief of emergencies (DIRE) is being developed by the Inter-Agency Procurement Services Office (IAPSO). DIRE will contain information on reliable suppliers of relief items, identified by the participating organizations as a result of competitive bidding.

Available from: World Health Organization, Division of Emergency and Humanitarian Action, 1211 Geneva 27, Switzerland.

Essential Drugs Monitor

Management of Uncomplicated Malaria and use of Antimalarial Drugs for the Protection of Travellers, WHO/MAL/96.1075, 1996, 98 p.

Early diagnosis and prompt treatment are fundamental to malaria control and need to be available wherever malaria occurs. Correct treatment of malarial disease will shorten its duration and largely prevent the development of complications and death. The worsening problems of drug resistance in many parts of the world, and the limited number of antimalarial drugs available, have led to increasing difficulties for the provision of adequate disease management. It is now recognised that most endemic countries will have to face the unavoidability of some resistance to the antimalarial drugs used to treat uncomplicated malaria. This highlights the importance of appropriate diagnosis to identify early treatment failures and target alternative drugs to such cases.

Each country needs an antimalarial drug policy in order to provide effectively early diagnosis and prompt treatment. Such policies need to take into consideration: the epidemiological factors that affect the distribution of the parasite and its pattern of drug resistance; the characteristics of the health services including those in the private sector; the levels of health care at which different drugs will be available; the risks and benefits of different drugs regimens, adherence to them and their cost; and logistics and affordability of drug delivery.

Guidelines addressing the broad aspects of such policy development have already been developed by WHO, (*Antimalarial Drug Policies*, WHO/MAL/94.1070, 1994). This new document complements the 1994 guidelines by: evaluating current approaches for malaria diagnosis; covering the principles of therapy and ancillary treatment; evaluating the roles of currently used antimalarial drugs; and providing recommendations and regimens for the use of antimalarial drugs, with reference to specific target groups.

Available, free of charge, in English, (French and Spanish in preparation), from: World Health Organization, Division of Control of Tropical Diseases, 1211 Geneva 27, Switzerland.

Do's and Don'ts of Medicines, Consumers' Association of Penang, 1995, 168 p.

This publication alerts consumers to the fact that the medicines they are taking to cure one ailment may cause another. The authors argue that the widespread belief that health can be found in a pill leads to overdependence on or abuse of drugs and blinds people to their potential dangers.

The book first addresses the dangers of overprescribing and looks at some examples of drugs with dangerous side effects. It describes how to give medicines to children, how to choose a doctor, and what rights patients have. It also lists the most common types of drugs, their uses, possible side effects and necessary precautions.

The publication also discusses what the authors view as the unethical dumping of drugs in developing countries by multinational pharmaceutical companies. It makes recommendations to governments on the actions they should take to ensure greater protection for consumers. These include the adoption of an essential drugs list, the use of generic drugs, clear labelling on all medicines and a ban on hazardous drugs.

The publication concludes by examining the benefits of natural healing and describes simple "alternative" remedies for common ailments.

Available from: Consumers' Association of Penang, 228 Jalan Macalister, 10400 Penang, Malaysia.

Quality Assessment of Natural Remedies, NLN Regulatory Seminars 1995, NLN Publication No.40, Nordic Council on Medicines, 1996, 52 p.

The Nordic Council on Medicines chose Quality Assessment of Natural Remedies as the theme for the first in its series of seminars on subjects of current interest to regulators. Fifteen drug regulatory authority employees met in Finland from 22–23 August 1995. The publication reports their discussions on establishing a common platform for the Nordic drug regulatory authorities when handling marketing authorisation applications for natural remedies. The focus is on scientific criteria for quality assessment of the products, including the composition, method of preparation and GMP inspection of natural remedies, and control of plant materials.

An appendix describes the current systems for processing applications for marketing authorisations for natural remedies in Denmark, Finland, Iceland, Norway and Sweden.

Available from: Nordiska Läkemedelsnämnden (Nordic Council on Medicines), Box 1983, S-751 49, Uppsala, Sweden. Price: SEK130 plus SEK25 for postage and packing. For orders within the European Union also add 25% VAT.

Tuberculosis and Children, AHRTAG, 1996, 16 p.

The Appropriate Health Resources and Technology Action Group (AHRTAG) has published a special supplement to its quarterly newsletter, *Child Health Dialogue*, entitled *Tuberculosis and Children*. It provides health workers in developing countries with practical, up-to-date information on how to tackle this preventable disease. The supplement outlines the principles of TB control and provides clear guidelines on the detection, diagnosis, treatment and prevention of TB. *Tuberculosis and Children* complements another AHRTAG publication on tackling TB and HIV – *Aids Action* No.31.

Available from: AHRTAG, 29–35 Farringdon Road, London EC1M 3JB, UK. Price: For individuals in Europe, North America, Australasia and Japan £2.50 each or £4.50 for both publications. Available free of charge to readers in developing countries.

Tuberculosis and HIV. A Clinical Manual, A.D. Harries, D. Mahar, WHO/TB/96.200, 1996, 135 p.

This manual provides a pocket-sized guide to the clinical management of tuberculosis, particularly in patients suffering from HIV co-infection. It promotes the best possible diagnosis and treatment in low-income countries where prevalence is high, case loads are heavy and laboratory support may be limited. With these needs in mind, the manual combines the latest scientific knowledge with authoritative advice based on extensive field experience in several of the hardest hit countries.

Though primarily addressed to clinicians working at district hospitals in sub-Saharan Africa, the publication is also suitable for use in areas of Asia and South America where the problem of tuberculosis and HIV co-infection presents a growing clinical challenge.

Available in English, (French and Portuguese in preparation), from: World Health Organization, Distribution and Sales, 1211 Geneva 27, Switzerland. Price: Sw.fr.12/ US$10.80, and in developing countries Sw.fr.8.40.

Managing Drug Supply. The Selection, Procurement, Distribution, and Use of Pharmaceuticals, (2nd ed.), J.D. Quick, J.R. Rankin, R.O. Laing, R.W. O'Connor, H.V. Hogerzeil, M.N.G. Dukes, A. Garnett (eds.), 1996, 832 p.

Improved policy decisions and management of essential drugs can make a positive impact on the health of a nation. *Managing Drug Supply* provides health planners and managers with the insights and tools to manage their pharmaceutical expenditures more rationally. Since the first edition was published in 1981, this 600-page handbook has been translated into French and Spanish, and has become a standard in the field of essential drugs management in developing countries. The first edition has been used by organizations such as UNICEF; as a reference manual by ministries of health, nongovernmental organizations and private consultants; and in training programmes in the USA, Europe and developing countries.

The new edition has been extensively revised and expanded in collaboration with the Action Programme on Essential Drugs (and other WHO programmes). It provides up-to-date descriptions of the process of drug selection, procurement, distribution and use. Policy and the economic environment in which pharmaceuticals are used are also critically examined using current management experience and procedures from around the world.

Illustrated with over 300 figures, tables, "how-to" boxes and sample forms, *Managing Drug Supply* can be used by pharmacists and other health professionals, policy makers and trainers. Glossaries, address lists, lists of further reading and references, and a comprehensive index offer the reader tools for research and follow-up.

Available from: Kumarian Press Inc., 14 Oakwood Avenue, West Hartford, CT 06119-2127, USA. Price: US$84.95 (developed countries) and US$22.95 (developing countries).

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

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

- India's ***National Essential Drugs List***, 1996. Ministry of Health. Based on WHO's Model List (see p. 6 for more details).
- Madagascar's ***Liste des Médicaments Essentiels à Madagascar***, 1996. Ministère de la Santé. Drugs by generic name in 27 therapeutic groups with dosage form and level of use. Includes a list of materials and equipment.
- Pakistan's ***Drug Information Sheets***, 1996, Ministry of Health. Details of indications, contraindications, side-effects, precautions and dosage of drugs in the Essential Drugs List.
- Republic of Yemen's ***National Standard Treatment Guide***, 1996. Ministry of Public Health. For use in first and second level health facilities. Includes a section on prescribing guidelines.

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Drug bulletins and newsletters

- WHO's latest newsletter is ***The TB Treatment Observer*** (see p. 6 for more details).
- Health Action International has brought out the first issue of ***HAI-Lights***, to replace ***HAI-Europe Update***. The new publication will continue to provide news and information about the HAI Network, but will also describe how groups have used materials – developed by themselves or received from HAI-Europe – to raise awareness and bring about policy change.

WORLD TRADE

Patenting pharmaceuticals: a new global order

Carlos M. Correa*

This article briefly reviews some of the key provisions of the GATT Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) in relation to the pharmaceutical sector, with a focus on their implications for developing countries. It is a summary of a recently issued WHO discussion paper (see below).

The United Nations General Agreement on Tariffs and Trade (GATT) was created in 1948 to liberalise trade in the post war era. Its international agreements were developed in a series of world trade negotiations known as "rounds", the most recent of which, the Uruguay Round, was finalised in 1994 after discussions lasting seven years. The Act establishes the World Trade Organization (WTO) whose member countries will implement the principles and provisions laid down in the Agreement.

The agreements contained in the Final Act of the Uruguay Round will have a significant impact on the global production and marketing of goods and services. An Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) was negotiated as part of the Uruguay Round. It is this component of the Round's Final Act which may have the greatest implications for the production of and access to drugs, especially in developing countries.

Major patent provisions

The provisions on patents contain the most explicit obligations for member countries and will have considerable impact on the drugs sector, although in varying degrees in different countries. One of the obligations is to grant both product and process patents in all fields of technology, thus eliminating the division between countries which grant patents to the pharmaceutical industry and those which do not. The Agreement also requires that member countries establish a minimum of 20 years' patent protection.

What is patentable and what is not, especially in relation to biotechnological innovation, is discussed, as is patentability in relation to a product's origin and the interrelationship between patents of the product and patents of the process. Exceptions to exclusive rights conferred by patents and granting of compulsory licences are both subject to certain conditions under the Agreement (see below).

Other provisions of importance for the pharmaceutical sector are the reversal of the burden of proof, where the party charged with violation is considered guilty until able to prove its innocence, and that of "undisclosed information", which gives countries the possibility to safeguard information submitted for approval of a product in order to protect it from what may be considered unfair competition.

Transition period

After the TRIPS Agreement became effective on 1 January 1996, all member countries of WTO had a one-year transition period within which to fulfil their obligations under the Agreement. Developing countries which join the WTO have four additional years (total of five years) and least developed countries 10 additional years (total of 11 years) to comply with the provisions of the Agreement. Transitional periods are also provided both retrospectively and prospectively for specific acts within the provisions relating *inter alia* to pharmaceuticals.

Dispute settlement

An innovation of the Uruguay Round is to be found in the way in which disputes are settled. Previously, these were subject to "positive consensus" at each stage of the dispute process. The principle now in force is that of "negative consensus" which will allow each stage of the process to proceed unless there is a consensus against it.

Photo: L. Ople

The Final Act of the Uruguay Round being signed in Marrakech in 1994 by Mr Pranab Mukherjee, India's Minister of Commerce at the time

Protection of public health

Finally, the principles embodied in Article 8 of the Agreement relating to the formulation or amendment of domestic laws and regulations, through which the Agreement must be implemented, explicitly recognise that measures necessary to protect public health may be adopted by countries, providing they are consistent with the Agreement's provisions and implemented within the time limits laid down.

Conclusions

Following a detailed analysis of the effects of the new intellectual property rights relating to pharmaceuticals, especially in developing countries, the study concludes that:

- ➤ although patent protection of pharmaceutical products will be enhanced this will not necessarily be to the benefit of all countries;
- ➤ it is likely that local production in developing countries will increasingly be replaced by imports of finished products, i.e. trade in drugs will increasingly replace direct foreign investment and the granting of licences to local companies;
- ➤ an increase in research and development of new drugs will not take place in either developed or developing countries;
- ➤ the transitional period for entry into force of the Agreement allows countries to continue to limit the introduction of pharmaceutical patents;
- ➤ measures to be borne in mind by countries when incorporating the provisions of the Agreement into domestic legislation are:

- ◆ including in domestic legislation a series of compulsory licences to act as an effective deterrent to monopolistic practices and to encourage access to licences by local companies under reasonable conditions (see Box);
- ◆ guarantee of the import of certain products on the principle of "international exhaustion" (e.g. if a patented product is sold in country A at a price of $100 and in country B the same product is sold at $80, this principle allows any interested party in country A to import the product from country B without the consent of the patent's owner);
- ◆ exclusion from patentability of certain substances;
- ◆ restriction of the reversal of the burden of proof to process patents for new chemical entities. ❑

Compulsory licences

The Agreement grants members the right to compulsory licences on certain grounds. These include:

Public health and nutrition or other reasons of public interest

Article 8 ("Principles") of the Agreement specifically recognises the right of members to "adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development..." Many countries, including some developed countries, provide for such compulsory licences in their legislation.

National emergency and extreme urgency

This is specifically mentioned in Article 31(b). It could also be considered to be covered by other general formulations such as "public interest". In such cases, prior negotiations with the right holder can be avoided.

Public non commercial use

In this case, a government is directly interested in using the patented invention for non commercial purposes.

Anti competitive practices

Compulsory licences can be granted to prevent abuse of a dominant market position.

Refusal of a voluntary licence

The TRIPS Agreement also authorises the granting of a compulsory licence when a patent holder refuses a reasonable commercial offer, which he has been given a reasonable amount of time to consider.

Other grounds

The Agreement does not limit the grounds for granting compulsory licences: domestic law can define the grounds for granting such licences, including those that are not mentioned in the TRIPS Agreement, which is only indicative in this respect.

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*The full discussion paper, C. M. Correa, **Uruguay Round and Drugs**, WHO Task Force on Health Economics/Action Programme on Essential Drugs, Geneva, 1996, can be obtained, free of charge, from: Action Programme on Essential Drugs, World Health Organization, 1211 Geneva 27, Switzerland. Fax: +41 22 791 4167. E-mail: DAPMAIL@WHO.CH*

Further reading

Further information about the GATT Agreement, WTO and TRIPS can be found in the following publications:

- Evans P. Unpacking the GATT: a step by step guide to the Uruguay Round. London, International Organisation of Consumers Unions (now renamed Consumers International), l994 (see Published Lately for further details)
- Kinnon CM. WTO: What's in it for WHO? WHO Task Force on Health Economics. Geneva, World Health Organization, 1995
- Effets de l'Uruguay Round sur les pays en développement (4 volumes): No.l Evaluation et perspectives; No.2 Synthèses des études par pays; No.3 Rapports par pays; No.4 Les Mesures suisses de politique commerciale et de coopération au développement. Geneva, Institut Universitaire d'Etudes du Développement, 1995 (only available in French)
- GATT TRIPS and the pharmaceutical industry: a review. Geneva, International Federation of Pharmaceutical Manufacturers Associations, 1995
- GATT – what it is, what it does. Geneva, GATT, 1992
- An analysis of the proposed Uruguay Round Agreement, with particular emphasis on aspects of interest to developing countries. Geneva, GATT Secretariat, MTN.TNC/W/122 MTN.GNG/W/30, 1993. Unpublished document
- Trading into the future: WTO, the World Trade Organization. Geneva, World Trade Organization, 1995. Unpublished document
- The Uruguay Round. Geneva, GATT, 1992
- The results of the Uruguay Round of Multilateral Trade Negotiations: the legal texts. Geneva, World Trade Organization, 1995. Unpublished document