

# ***Drug rationalization: now for the hard part***

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*In 1995 a national drug policy was finalized in Nepal. The authors outline the measures that were recommended for its implementation and the activities that have so far been undertaken. Much remains to be done, most notably in assisting, coordinating and supervising these activities.*

About 10 000 pharmaceutical products are marketed in Nepal. Some drugs are available in hundreds of brands and there is widespread prescribing by proprietary names. Many people lack regular access to essential drugs, while huge quantities of non-essential products are on sale. In 1991–92, liquid vitamins and tonics were the highest-selling items, accounting for 10.3% of retail drug sales. Only about 20% of the drugs used are produced in the country, although a range of tax and tariff incentives is on offer to stimulate the growth of the domestic pharmaceutical industry.

Self-medication is quite common in Nepal and some 90% of drug sales occur in the private sector, mainly through retailers without training in pharmacy. For this reason the Department of Drug Administration offers a drug retailers' orientation course on the interpretation of prescrip-

tions, the storage and dispensing of drugs, and the provision of advice for customers. Drug utilization studies have been conducted by the Department, the Institute of Medicine, and the International Network for Rational Use of Drugs.

The supply of drugs to government health facilities in any given year is largely determined on the basis of orders made during the preceding year rather than on requirements estimated from such criteria as past consumption, prevailing diseases, standard treatment schedules and the sizes of the populations served. Dispensing facilities are inadequate, stock control procedures are poor, and drug storage is unsatisfactory. The annual allocation of drugs to health posts and other government facilities usually lasts for less than six months, with the result that incomplete courses of drugs are frequently dispensed.

The Royal Drug Research Laboratory, which is the only governmental quality control facility, does not have an adequate testing capacity. No serious attempt has been made to perform comprehensive drug inspection, partly because of a shortage of trained personnel. Most of the drugs officially categorized as prescription-only medicines are actually sold over the coun-

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ter. There is no mechanism for post-marketing surveillance and the monitoring of adverse drug reactions.

Drug companies conduct aggressive promotional activities over which there is almost no control, notwithstanding the existence of a drug advertising code. Drug companies have not been required to register specific indications of their products with the Department of Drug Administration, which is responsible for enforcing the 1978 Drug Act governing the production, distribution, sale, exportation, importation, quality and use of pharmaceuticals. There is a pharmaceutical sales representative for about every five doctors. Efforts have recently been made to provide prescribers and consumers with information and education about the rational use of drugs but they have not been sufficiently comprehensive.

### **Essential drugs**

A national list of essential drugs was published in 1986, and a revised version indicating 259 drugs and vaccines, together with dosage forms and strengths, appeared in 1992. Corresponding lists were produced for various levels of the health services. A standard drug treatment schedule for health posts was issued in 1988 and a revised version was published five years later. Unfortunately, these documents are often unavailable in government health institutions, and even where they are it is not clear to what extent they are being used. Furthermore, some of the drugs supplied to these facilities are not the same as those listed. Over the past 12 years, bans have been placed on 65 ineffective or harmful drugs or irrational combinations.

Cost-sharing and cost recovery schemes are being tried with a view to achieving sustainable availability of essential drugs in government health facilities through

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community participation. Some partial successes have been obtained in this area.

### **National drug policy**

A participatory approach was adopted for the development of a comprehensive drug policy. A draft document was prepared in 1992 and extensively reviewed by national and international experts. At a seminar in 1994 it was discussed by officials, academics, health workers, pharmacists and representatives of nongovernmental organizations, with reference to:

- policy objectives;
- an essential drugs list, rational drug use, and drug information;
- the drug industry, traditional medicines, and manpower development;
- quality assurance and regulatory control;
- drug management, procurement, storage and distribution.

This led to a revised draft policy being presented to the country's Drug Consultative Council, which made further refinements. The principal aims of the definitive policy adopted in 1995 were to do the following:

- achieve 80% self-reliance within 10 years in the production of essential drugs by promoting and supporting the domestic pharmaceutical industry;
- ensure good quality by monitoring manufacturing practices, adhering to the WHO certification scheme, strengthening the Royal Drug Research Laboratory, and evaluating marketed products;
- ensure uninterrupted nationwide availability of medicines at affordable prices through attention to procurement, transportation, storage, sales and distribution, together with cost recovery schemes and price regulation mechanisms;
- promote the proper use of drugs through training, education and the development of a drug information system;
- encourage the training of pharmacists;
- promote the production of traditional medicines, and evaluate and regulate their safety and efficacy;
- improve coordination by establishing a pharmaceutical affairs unit in the Ministry of Health;
- improve regulation by setting up regional offices of the Department of Drug Administration.

### **Implementation**

These goals clearly require an implementation plan defining how, when and by whom they are to be achieved, taking into account the country's financial, manpower and other limitations, which make it impossible to deal with all the elements of policy simultaneously. It is necessary to prioritize the aims, define them quantitatively, and monitor and evaluate perform-

ance. Pending the emergence of such a plan, the following activities have been initiated.

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- A cost-sharing scheme, the Community Drug Programme, has been introduced in a small number of pilot districts by the Ministry of Health and the Ministry of Local Development, with the objective of maintaining drug availability in government health facilities. The intention is that it should gradually be expanded to cover the whole country. This programme is supported by Kreditanstalt für Entwicklung (Germany), the Nippon Foundation (Japan), and UNICEF.
- The Ministry of Health, with support from the United States Agency for International Development, is working on the improvement of drug logistics management.
- The Department of Drug Administration, supported by the United States Agency for International Development and WHO, is developing a computerized drug registration database.
- The capacities of the Royal Drug Research Laboratory are being improved, with help from the Japan International Cooperation Agency and WHO.
- A drug information network has been developed by the Department of Drug Administration, the Institute of Medicine, the Nepal Health Research Council, the Nepal Chemists' and Druggists' Association and the Re-

source Centre for Primary Health Care, with assistance from the United States Agency for International Development and other organizations.

- A university in the private sector is offering a four-year degree course in pharmacy.
- The Department of Drug Administration, supported by the German Technical Cooperation Agency and the United States Agency for International Development, is developing an intervention programme for the promotion of rational drug use in public health facilities.
- Revised versions of the national list of essential drugs and the standard drug treatment schedule for health posts are expected to be published soon, and a national formulary is being developed.

These and other activities should help to achieve some of the goals of the drug policy, but they would undoubtedly be more effective if assisted, coordinated and supervised by a drug policy implementation committee and a pharmaceutical affairs unit, bodies that it would therefore be highly desirable to set up as soon as possible.

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Nepal's drug policy offers a prospect of rationalizing the country's pharmaceutical sector. An action plan is now required which establishes priority goals, strategies, responsibilities, time frames and financial commitments. Collaboration between government, academia, manufacturers, health workers, pharmacists and consumers is necessary in order to bring this about. ■