What action for rational drug use?

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The author reviews the use of medicinal drugs in Pakistan and suggests measures for improving the present situation. Particular attention is given to the selection, availability and rational use of essential drugs. Reference is also made to procurement policy, quality control, drug registration and control, the education of doctors and pharmacists, the dissemination of drug information, prescribing practices, and the availability of prescription drugs without prescription.

In Pakistan some 12,000 pharmaceutical products are registered and available. The country’s drug market is worth about Rs 20,000 million (US$ 650 million) a year. Of the 275 pharmaceutical manufacturers active in Pakistan, 30 are multinationals and the rest are local; however, 35% of the money earned from drug sales goes to Pakistani firms.

The Drug Act of 1976 deals with the manufacture, sale, importation and export of allopathic drugs. Traditional medicines, which are common in Pakistan, are not covered because no rules have been established for their manufacture and sale; they can be imported without restriction. The Drug Act requires every drug manufactured or marketed in the country to be registered with the Ministry of Health. The four provincial governments regulate sales, while the federal government frames rules and regulations on such matters as licensing, registration and advertising.

Selection and procurement of drugs

The provincial and federal governments have established committees with responsibility for selecting generic drugs in response to requests made by peripheral health units and teaching hospitals. Whereas drugs are advertised for purchase under their generic names, the majority are supplied under trade names. Most teaching hospitals have their own lists or formulae of drugs, the number of which is usually smaller than that on the provincial list. Hospitals are permitted to purchase drugs on the market up to a value of about 20% of the money allocated to them for drugs.

Lists are prepared in each of the country’s four provinces by experts representing pharmacy, pharmacology and the clinical specialties in various units, including teaching hospitals. Each province purchases drugs in bulk, and stores and distributes them. The drugs in the provincial stores are received under both generic and brand names. Certain university hospitals have drawn up their own lists of small numbers of drugs under generic names. Institutions attached to the federal Ministry of Health follow a similar pattern of purchase.
The country's first list of essential drugs, comprising approximately 400 generic names, was issued in 1994, and has recently been revised and updated. Now the Federal Health Ministry is making efforts to ensure that all government health institutions procure medicines in accordance with the National Essential Drugs List. A concerted effort should be made by the federal government to convince the institutions for which it is directly responsible, and the provincial governments, of the desirability of using the essential drugs list and purchasing by generic names.

**Quality control**

Although there has been a general improvement during the last 25 years in the quality of drugs manufactured and imported, a tendency still exists for products to deteriorate once they enter the trade channels because of the hot climate and inadequate storage facilities. In order to improve matters, close collaboration is needed between the drug control authorities and the schools of pharmacy to ensure availability of safe and effective drugs of good quality to the public.

The Federal Drug Registration Board comprises representatives of doctors and pharmacists. Drugs are registered if they have satisfied the evaluation and registration procedures in the countries of origin and are available for use; studies are not required in Pakistan because of the absence of clinical pharmacological evaluation facilities. In many instances, products have been registered simply on the basis of opinions expressed by senior professors. There is thus a clear need to create facilities for clinical evaluation. This means establishing posts for clinical pharmacologists in medical colleges. The College of Physicians and Surgeons in Karachi has established a fellowship programme in clinical pharmacology, and has initiated work to assess adverse drug reactions in the Pakistani population. In order to promote the rational use of drugs to the greatest possible extent the College needs to engage fully qualified and experienced clinical pharmacologists.

Pakistan has no independent drug control authority. Such an authority, responsible for evaluating the quality, safety and efficacy of drugs, would require the services of experts. More field staff than are now available would be needed for monitoring the importation, export and manufacture of pharmaceuticals, with particular reference to quality. A higher level of chemical and biological expertise than at present would be necessary in analytical control laboratories. Information from outside the country, especially from WHO and national drug control authorities, is also required. Clinical pharmacological expertise would be vitally important.

A drug control authority would communicate information about products already on the market or under consideration for registration to physicians, pharmacists and professional organizations. The information would include specific issues relating to drugs which might be of concern to the public. The activities of a drug control authority in Pakistan would demand a large financial commitment. In some countries charges for specific services are made by independent drug control authorities.

By and large, the medical profession in Pakistan regards drug control as inadequate. Serious consideration should be given to the provision of resources for setting up an independent drug control body.

**Availability and use of information**

Effective education on rational drug use is vitally important in the country's schools of
of the Network for the Association of Rational Use of Medications in Pakistan. Also of value are the Pakistani editions of the Journal of the American Medical Association and the British medical journal.

Coordination is required between the Ministry of Narcotics Control and the Ministry of Health in order to reduce both the demand for illicit drugs and the illicit demand for licit drugs, and special attention should be given to the provision of information on these matters to health care professionals. The resource centre of the Ministry of Narcotics Control holds valuable data which should be utilized by the Ministry of Health and widely disseminated.

Control of psychotropic, steroid and other drugs

Among the many concerns expressed by psychiatrists are the following.

- There are over 30 brands of benzodiazepines but only some 15 generic preparations.
- Alprazolam, available as Xanox and under four other names, is overprescribed by doctors and should be more strictly controlled.
- Bromazepam (Lexatonil) is available in 6-mg tablets, but tablets of 2 mg are needed as this is the usual dose.
- Phenoxytin is sometimes brought in from India because of its higher price in Pakistan.
- Injectable procyclidine is not available.
- The local formulation of buprenorphine and penta-zocine has been started and their prices have consequently fallen; unfortunately this has led to increased abuse of the drugs.
- Because imipramine and some antidepressants are available only in small doses, it is comparatively difficult to achieve the compliance of patients who have to take more than one tablet daily.
The production and availability of narcotic drugs such as morphine and pethidine are controlled by making them available through hospitals and by prescription only in the public sector. Psychotropic drugs, especially tranquillizers, should be subjected to similar control as soon as possible. Discussions between the federal and provincial governments on how to achieve this have been initiated. Many physicians consider that steroids and antibiotics also require to be rigidly controlled, as problems have arisen through their irrational use.

Some drugs, including psychotropic products, can still be purchased without prescription. This situation has arisen because of the granting of sales licences to inadequately qualified persons. Most chemists and druggists are not graduates in pharmacy. The regulations on issuing licences should be changed so that only qualified pharmacists are permitted to sell drugs. Furthermore, persons in charge of drug stores should be trained to provide an improved service to the public.

The role of pharmacists

Three pharmacy faculties in universities in Pakistan have recently introduced clinical and medical subjects into their Bachelor of Pharmacy courses, a very beneficial step. While in Punjab there is one pharmacist per 200 beds in teaching hospitals and district headquarters hospitals, this level of provision is far from being achieved elsewhere in Pakistan.

Further efforts are needed to improve the training of pharmacists in relation to adverse drug reactions, drug utilization studies, prescription surveys and other areas associated with clinical medicine. Progress of this kind would allow pharmacists to cooperate with doctors and help reduce irrational prescribing. Pharmacists can be expected to become involved in preventive education, especially in connection with drug abuse and irrational prescribing. Doctors undoubtedly need advice on drug therapy to counteract the frequently aggressive approaches of medical representatives of drug firms.

The above observations suggest that the following steps should be taken in the interests of rational drug use in Pakistan.

- Licences for the sale of drugs should be issued only to pharmacy graduates, and rigid controls, similar to those applied to narcotics, should be adopted in respect of other products, especially psychotropics, antibiotics and steroids.
- Undergraduate medical education should include special attention to the rational use of essential drugs.
- Unbiased information on drugs should be made available to doctors in order to counteract the sales promotion activities of the pharmaceutical industry. Short compulsory courses for doctors should be organized by colleges of medicine and pharmacy and by scientific institutions, especially for re-registration every 5 years.
- A new and updated essential drugs list should be printed in sufficient quantities for distribution among medical students, doctors and other health care professionals.
- Clinical pharmacological services should be strengthened in the interests of pre-registration evaluation and post-marketing surveillance of drugs. This requires the creation of posts for clinical pharmacologists in medical schools and the provision of fellowships enabling doctors to pursue their training in other countries.
- Comprehensive data should be obtained on doctors' prescribing patterns. A pilot study on prescribing practices could be undertaken in large hospitals, and the information obtained could be used in workshops leading to observations on the effects of interventions.
- Improved facilities should be provided to strengthen the work of drug control.