DISCUSSION

A rational drug policy

P K SARKAR

Editor, *Bulletin on Drug and Health Information (BODHI),* 254, Block B, Lake Town, Kolkata 700089, India. e-mail: fha@cal.vsnl.net.in

Pharmaceutical companies have an important place in medical care, especially in India, a country where the mortality and morbidity due to various diseases of deprivation, communicable diseases in particular, are very high. Every year hundreds of people still die from malaria for which chloroquine is a cheap but effective remedy; thousands go blind due to lack of vitamin A, and millions suffer from endemic goitre due to iodine deficiency. We have also the largest number of people suffering from tuberculosis and leprosy in the world. At the same time, India is technologically developed enough to be self-reliant, with research capability for the discovery of new drugs. Unlike most other countries, responsibility for the pharmaceutical sector in India is shared by two ministries, the Department of Chemicals and Petrochemicals under the Ministry of Industry and the Directorate of Drugs Control under the Ministry of Health and Family Welfare.

Development of the drug industry in India

The foundation of the modern Indian pharmaceutical industry dates back to 1901 when the Bengal Chemical and Pharmaceutical Works was established in Calcutta (now Kolkata). However, till Independence, the country was dependent largely on drugs imported from Europe. After Independence, pharmaceutical manufacturers in India were encouraged to take up the manufacturing of basic drugs. Collaborations were established with manufacturers in the US, Switzerland, (West) Germany, Italy and the UK. During the 1950s and 1960s many manufacturing units were set up throughout India. The Soviet Union helped set up five units for manufacturing synthetic bulk drugs and intermediate chemicals, antibiotics, vitamins and hormones, surgical instruments and medical equipment under the public sector.

Today, in India, about 20,000 firms have licences to produce drugs and pharmaceuticals. Of these, about 200 units are responsible for over 40% of total drug production. Over the past few decades, the Indian drug industry has seen phenomenal growth and emerged as an exporter. It is estimated that the Indian drug market, at present, is worth more than Rs 100,000 million.

A drug policy

The first national drug policy emerged from the findings of the Hathi Committee which was commissioned to study the operations of multinational drug companies *vis-à-vis* indigenous companies and public sector undertakings. The committee's recommendations, released in 1975, included: nationalisation of multinational units, diluting foreign equities of companies coming under the Foreign Equity Regulations Act; earmarking some drugs for public sector undertakings; strengthening R&D activities; abolishing brand name drugs; issuing licences for formulations of only 117 drugs which the committee considered sufficient for the treatment of the majority of diseases in India; measures for drug quality control; disseminating unbiased drug information to prescribers and consumers; monitoring of adverse drug reactions, etc. However, the Hathi Committee also recommended differential mark-ups for essential and non-essential drugs. This recommendation had a lasting undesirable impact.

The first National Drug Policy was declared in 1978, and has been revised thrice since then, in 1986, 1994 and 2002. The question is: were these drug policies at all rational?

According to the WHO, a national drug policy should be based on relevant background information including the country's morbidity, mortality, health system, human resources, and the organisation of the drug sector. A (rational) national drug policy should include: a list of essential drugs; use of generic names of drugs; criteria for drug registration based on safety, efficacy, quality, health needs and cost; regulation, control and monitoring of drug prices and drug promotion; centralised bulk purchase of drugs using international tenders (for countries lacking manufacturing facilities), and national legislation on patents to exclude pharmaceutical products from patent protection. How does India's national drug policy measure up?

The 1978 Drug Policy

In 1978, the Government of India declared a drug policy supposedly based on the Hathi Committee report. However, the government diluted some of the Committee's recommendations and rejected others. This was soon followed by the declaration of the Drug Prices

Control Order (DPCO,1979) which brought 347 drugs under price control, dividing them into four categories according to how essential they were deemed to be, allowing maximum profit margins to the least essential drugs. The idea was that the lower profit margins from life-saving and essential drugs (Categories I and II) would be compensated for by the higher margins for Categories III and IV drugs. However, the result was that drug companies decreased and even stopped the production of life-saving and essential drugs and concentrated on the more profitable ones.

Drug policies 1986 and after

Some stated goals of the 1986 Drug Policy were to ensure availability of essential life-saving and prophylactic medicines at reasonable prices; strengthen quality control and promote the rational use of drugs; encourage investment in new technologies and cost-effective production; and strengthen the indigenous capacity for production of drugs. The 1987 Drug (Prices Control) Order reduced the number of price control drugs from 347 to 142 and increased the maximum profit margins for these drugs. Special concessions to ayurvedic drugs resulted in thousands of such formulations, with some well-known allopathic formulations being marketed as ayurvedic drugs. The 1995 DPCO dropped the following drugs essential for public health: ferrous sulphate for anaemia, and most drugs for tuberculosis, malaria, leprosy, rheumatic heart disease, rabies vaccine, cancer, tetanus, etc.

The pharmaceutical policy (2002) calls for further relaxation of production and price controls. Production controls have now mostly gone except for bulk drugs produced by the use of recombinant DNA technology, bulk drugs requiring *in vivo* use of nucleic acids, and specific cell/tissue targeted formulations. It is expected that less than 40 drugs will remain under price control.

The results

In the absence of a clear, comprehensive and rational drug policy, we continue to see a distorted pattern of drug production and the proliferation of non-essential, irrational and harmful drugs. Indian markets are flooded with over 100,000 formulations; there is no system of central registration of these formulations. These drugs are sold under numerous brand names rather than their generic names. There has also been a phenomenal increase in drug prices.

Despite the phenomenal growth of the drug industry during the past five decades, the availability of modern drugs is still low. For example, in 1984 only 5%–6% of the population could afford the modern drugs they needed; another 25% had limited access to essential drugs. A majority of the people living in rural areas and urban slums, the main victims of endemic and epidemic diseases, had little or no access to modern drugs. With the predicted increase in the cost of drugs after joining the WTO, the problems are likely to go out of control.

Since 1983, the government has issued various orders banning several harmful and/or useless formulations marketed in India, but to little effect. Drug and health activist organisations, under the auspices of the All India Drug Action Network (AIDAN), went to the Supreme Court demanding implementation of the ban. Some constituent bodies publish drug information bulletins for prescribers. In general, representatives of pharmaceutical companies are the only source of information to prescribers in remote areas. The government has taken little initiative to fulfil its statutory function to monitor manufacturers' promotional literature and has taken no steps to supply objective and unbiased drug information to prescribers.

Drug and health activist organisations have recently intervened in a petition challenging the government's recent move to further curtail the number of drugs under price control. At the heart of these efforts is the principle of entitlement. Neither the Constitution nor the National Health Policy guarantees the right to health or to medical care including affordable and appropriate drugs. The community of health professionals must recognise this right and help people exercise it.

Suggested reading

1. World Health Organization. *Indicators for monitoring national drugs policies—a practical manual*. Geneva: WHO/DAP/94.12, 1994.
2. *How to develop and implement a national drug policy*. 2nd ed. (updates and replaces *Guidelines for Developing National Drug Policies*, 1988) Geneva: WHO, 2001.
3. *The world drug situation*. Geneva: World Health Organization, 1988.
4. Majumdar JS. *Multinationals in drug and pharmaceutical industry in India*. 2nd ed. Patna: All India Chemical and Pharmaceutical Employees Federation, 1979.
5. Hamrell S, Nordberg O (eds). *Development Dialogue: 1985:2*. Sweden: Dag Hammarskjold Foundation, 1995.
6. Najmi Kanji *et al*. *Drugs policy in developing countries*. London: Zed Books, 1992.
7. Mukhopadhyay A. (ed). *Report of the Independent Commission on Health in India*. New Delhi: VHAI, 1997.
8. *Measures for rationalisation, control and growth of drugs and pharmaceutical industry in India*. New Delhi: Government of India, Ministry of Industry, Department of Chemicals and Petrochemicals, 1986.
9. *Modification in Drug Policy: 1986*. New Delhi: Government of India, Ministry of Industry, Department of Chemicals and Petrochemicals, 1994.
10. *Indian pharmaceutical guide*. 27th ed. New Delhi: Pamposh Publications, 1989.
11. *Rational Drug Policy Statement*. New Delhi: All India Drug Action Network, 1984.
12. Collective petition (2003) by AIDAN, Locost and Jan Swasthya Sahyog to the Supreme Court challenging the government's arbitrary reduction in the number of drugs under price control.

This article is based on a presentation at the XXVIIth Indian Social Science Congress of the Indian Academy of Social Sciences, Kharagpur, December 5, 2003.