

Pharmaceutical Policy, 2001

Industry Wish-List

In attempting to ensure that the pharmaceutical industry is able to function profitably, and perhaps, efficiently, policy-makers have completely ignored the health concerns that are integrally linked to the contours of the drug policy.

ANANT PHADKE

The Draft Note for the cabinet committee on Economic Affairs, titled 'Pharmaceutical Policy 2001', follows the old pattern of exclusively focusing on economic issues related to the drug industry. It primarily deals with pricing of drugs and profitability. This time, the additional concern is the increased focus on making the Indian drug industry on par with the international standards. Despite the repeated demand from consumers and health groups that the health ministry be actively involved in the preparation of the pharmaceutical policy, this draft policy has been prepared only by the ministry of chemicals and fertilisers, totally excluding issues of rationality of drug production.

Briefly speaking this 'Note' has the following features:

Complete surrender to the MNCs: It sanctifies the 'liberalisation' steps taken since 1991 – abolition of industrial licensing barring a few exceptions; dereservation of the five drugs hitherto reserved for the public sector and opening of the public sector to foreign competition; automatic approval of foreign investments even for 100 per cent foreign collaboration; automatic approval of foreign technology agreements. Industrial licensing has been abolished except for three technologies – recombinant DNA technology, in vivo nucleic acid use, specific cell/tissue targeted formulations.

Increased incentives and provisions for research for enhanced international competitiveness: (a) Permission to increase prices by 5 per cent extra for drug companies which comply with suggested 'gold standards' of investing at least 5 per cent of the turnover of the company in R and D, at least Rs 10 crore per annum for innovative research; employing at least 100 research scientists in India; and of having at least 10 patents for research done in India.

(b) Setting up of Pharmaceutical Research and Development Support Fund (PRDSF) with the ministry of finance contributing Rs 150 crore as 'Plan Fund' for the creation of the 'R and D fund'. (c) To enhance international competitiveness, certain measures will be taken, like mandatory WHO/Good Manufacturing Practices Certification Scheme, attaining international standards for clinical testing. For products manufactured under WHO-GMP certification, additional 8 per cent cost be allowed in estimating cost of production and further up to 2 per cent for improved packing. We have to see whether all the details of the WHO-GMP certification standards are relevant to Indian conditions. There cannot be any compromise on minimum standards. But beyond this, in pursuit of promoting exports, if standards are set on par with developed countries, the drug prices would go further out of the reach of the majority of people in India. Hence, we should question this move.

Reduced span of price-controlled drugs: Only about 37 bulk drugs accounting for about 20 per cent of the market-sale, would be under price-control, as compared with the 74 bulk drugs accounting for about 40 per cent of the market being under price-control today and 343 drugs under price-control in 1985. Newer, 'liberal' criteria for selection of bulk drugs under price-control have done this trick.

Increased profitability: The Maximum Allowable Post-manufacturing Expense (MAPE) would be 100 per cent for indigenously manufactured drugs. Currently only category II and III drugs are allowed 100 per cent MAPE. For imported formulations, the selling price can be up to 150 per cent of the landed costs. The present provision as per the Third Schedule of the Drug Price Control Order 1995, of limiting the profitability of drug companies, would be done away with. There would be some exemptions (see section B2.2)

even for the limited number of 37 bulk drugs to be under price-control. Thus overall, the drug companies have been given a free hand to jack up prices. These above four are the main provisions in brief, of the 'Pharmaceutical Policy 2001'. There are a few other provisions, which are of not much significance.

What Should Be Our Critique?

A critical response to this draft note is twofold, raising issues on both the health and economic aspects. On the health aspect, the exclusion of the policy issues related to the rationality/irrationality of various drug-formulations sold in India should be strongly protested. Secondly, the following long-standing demand of health groups about the socio-medical rationality of drug production in India have been ignored: (1) Elimination of all drugs and formulations not recommended by standard textbooks and other authorities; (2) Elimination of fixed dose combinations not recommended by standard textbooks and other authorities; (3) Priority and incentives to the production of essential drugs, especially to drugs for primary health care; (4) Abolishing of all brand names – drugs to be sold only under generic name, with the company's name in the brackets; (5) Reviewing of all the drugs every three years to eliminate obsolete drugs; (6) Strict ethical guidelines for drug-research; (7) Commercial production of any drug claimed to be ayurvedic, be allowed only after the scrutiny of its rationality by the council for Indian system of medicine (ISM); (8) Strict regulations for ethical promotion and marketing of pharma-products. Detailed formulations have been made by health groups in their earlier deliberations and demands; (9) Proper system of post marketing surveillance for adverse drug reactions; (10) Proper system of compulsory continuing medical education (CMIE) for medical and paramedical professionals in rational therapeutics.

These demands need to be put forth forcefully. The 'Pharmaceutical Policy 2001' it may be pointed out does not even mention these crucial aspects.

Self-reliance, which was one of the principal concerns of the Hathi Committee report and which was an important element of the earlier drug-policy statements, does not even find a mention in this 'Note'. For the current decision-makers, a globalised economy means

complete domination by the foreign multinationals. Restrictions on majority-owned foreign companies in the production of those drugs for which know-how exists with the Indian companies are a must. Foreign companies should be allowed only if they are willing to provide superior know-how at reasonable cost to the Indian companies.

In today's globalised economy, distinction between the role of 'Indian' and 'foreign' companies has been blurred to a certain extent. But there is no case for throwing overboard the concept and strategy for self-reliance. Complete domination by foreign MNCs is neither inevitable nor of course desirable.

Drug consumer groups have long argued for price-control on drugs for two valid reasons: (1) drugs are part of essential commodities, are life-saving; and (2) the consumer has no choice, but has to buy medicines once the doctor prescribes it. Hence consumer resistance is very low in purchase of medicines. No amount of so-called liberalisation would negate the above rationale. Hence the need for control of drug prices continues. The drug price control is today too complicated because of the plethora of thousands of irrational fixed dose combinations being marketed. If all these irrational fixed dose combinations are weeded out, price-control will be far less complicated.

Even within the existing drug production pattern, there is no case for further concessions to the drug industry by reducing the number of drugs to be price controlled. Further decontrol of drug prices should be opposed by concretely exposing the irrational nature of the new measures of further price decontrol. The new formula for deciding which bulk-drugs will be price-controlled, is as follows: For bulk-drugs with a sale of Rs 5 to Rs 20 crore, the drug will be price-controlled if a formulator controls more than 50 per cent of the market; and for bulk-drugs with a sale of above Rs 20 crore, the drug will be price-controlled if a formulator controls more than 90 per cent of the market.

Even if price-control is to be restricted to drugs which are produced or sold monopolistically, both these figures of cut-off sale value and of per cent control by one formulator are arbitrary. There should be no cut-off value for sales figures. Any drug should be subject to price-control, whatever may be its sale, if it is produced or sold monopolistically. Secondly, the cut-off value to decide monopolistic control cannot be set arbitrarily at 50 per cent

or 90 per cent control by one formulator. Internationally, it has been established that if more than half of the market of a product is controlled by five or less number of companies, the product is deemed to be under monopolistic control. This criterion be applied to the bulk drug market in India, if it is decided that price-control is restricted only to drugs which are monopolistically controlled. The above formula is for bulk drugs, from which ayurvedic drugs have been excluded. The method for controlling prices of formulations would continue as before, as per the 1995 DPCO.

Certain drugs would be exempt from price-control. The criteria for exemption are liberal, at the cost of the consumer. These criteria are (a) 15-year exemption for new drugs developed through indigenous R and D; (b) Exemption till expiry of the patent for drugs whose process has been patented under the Indian Patent Act 1970; and formulations involving new drug delivery systems registered under IPA 1970.

As per the DPCO of 1979, some drugs were allowed only 40 per cent mark up. Hence the drug companies were clamouring for exemption of certain drugs from price control. But now, as per the new proposed policy, all indigenously manufactured drugs would enjoy 100 per cent MAPE. Secondly these will be a monopoly due to

the patent coverage so that the prices will not be brought down by competition, below the levels decided by the new limit of 100 per cent MAPE. Hence, now there is no case for exemption from price-controls, if the MAPE is raised to 100 per cent; (c) 'Cost per day per medicine' being less than Rs 2.

This would mean commonly used essential drugs like aspirin, paracetamol, iron-folic acid, furazolidone, B' complex, etc, will all go out of price-control. This exemption should also be stoutly opposed. The fact that drug companies have been selling 75 mg tablet of aspirin at 75 paise per tablet, when the price should not be more than 20 paise, per day, shows once again that they cheat, exploit consumers whenever there is a chance. Removing price-control on those essential drugs whose per day cost is less Rs 2 is simply unacceptable.

Other provisions as regards ceiling prices, fixing prices of Scheduled Bulk Drugs, drug price monitoring, Drug Price Equalisation Account (DPEA) do not require any fresh comments. Thus overall, the new drug policy titled 'Pharmaceutical Policy 2001' is pro-industry, anti-people and devoid of any medico-social rationality. This should be opposed in whatever way possible. ■■■