Towards a Left Critique of New Drug Policy

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The long awaited new drug policy has prompted this piece so that RJH-readers may get some systematic idea about this issue, especially its economico-political aspect, albeit in a summary form. For a detailed treatment of the basic issues involved in the drug policy, readers may refer to some of the sources at the end. A special issue on Pharmaceuticals and Health is being planned in December, 1987 and will carry a substantial left analysis of issues in drug policy.

THE NDP represents a typical example of the 'new' thinking in the ruling class circle and the new method of functioning. First about the latter. A lot of show was made about consulting various experts and of giving a hearing even to the representatives of the All India Drug Action Network. (AIDAN). But all this facade meant nothing in practical terms; or perhaps the drug industry used 'tonic-M' much more liberally this time. The NDP was suddenly announced in a hurriedly convened press conference; bypassing the Parliament. The 'policy' consisted of only a breif statement amounting to about 1500 words—That's all!! When a lack of a detailed draft was criticised by all analysts, the government came out with a somewhat detailed 19-page announcement. When one reads this pamphlet a little carefully, it is clear that it was written *after* the 'policy' was announced. The press statement of the December 18, 1986 was not a summary of a policy document since no such document was ready the then.

For example, the press statement of December 18 says that. "A National Drug and Pharmaceutical Authority will be created. This authority will be an apex body which will have representation from all the concerned agencies including those from the industry. Among other things, it would go into the question of rationalisation of existing fomulations in the market including the banning of formulations of harmful nature. . ." When one looks for an elaboration of this point in the detailed policy announcement, to one's utter dismay and shock there is not even a mention of "representation from all the concerned agencies" nor of "banning the formulations of harmful nature"!! To release a brief statement to the press and then to prepare the main text is a mockery of the norms of even bourgeois democracy. The deletion of these to small concessions (announced in the press statement,) given to the movement for a Rational Drug Policy was perhaps on account of bowing to the pressure exerted by the drug industry to scrap these concessions. To silently drop certain measures already announced is shocking indeed.

The earlier policy of 1978 was based on the report of the famous Hathi Committee which had at least a few Members of Parliament (though there were no representatives of the concerned trade unions and of consumers.) The policy-making was done this time entirely by bureaucrats and technocrats. The Drug Consultative Committee of the Parliament was not involved. The content of this NDP is therefore as bad as its flimsy form. None of the issues central to the Drug Policy have been seriously considered except the ones related to profits and production increase. All the important issues have been adequately highlighted by different science and health groups, some of which were dealt with by the famous Hathi Committee more than a decade back. Instead of making progress beyond the Hathi Committee there has been a regression right from the basic stage. It is, therefore, not much of a surprise that the content of the policy is also reactionary.

Freer Hand to Multinational Companies

The drug industry in India in under the domination of the MNCs. The various ill-effects of these MNCs have been adequately proved by different studies—commercial exploitation of Indian consumers through transfer-pricing; huge outflow of capital through repatriation of profits in different forms, drain on the foreign-exchange account; huge social waste on account of extravagant selling expenses, disinformation of doctors, insistence on brand-names, production of irrational and hazardous drugs when the same drugs are not allowed in their parent country, etc. It is because of these ill-effects that the Hathi committee had recommended nationalisation of these MNCs. The Hathi committee's recommendation did not include confiscation (i e, nationalisation without compensation) or worker's control along with nationalisaton. But even this radical bourgeois recommendation was not accepted by the Indira government.

The New Drug Policy has on the contrary given further concessions to the MNCs. "For the production new bulk drugs, and drugs produced for exports, there will not be any restrictions on the MNCs, even though it is well known that MNCs tend to import penultimate products from their parent-companies at extravagant prices and hence are responsible for a drain on the Indian economy even for foreign exchange account. Production of penicillin, amoxycillin, cephalexin etc, has also been completely decontrolled except for FERA companies." But the hitch is, there are now only 3 FERA companies; the rest of the MNCs have now become 'Indian' because they have diluted their foreign-equity to less than 40 per cent as per the FERA. Out of these eight a further six have announced their intention to dilute their foreign-equity to less than 40 per cent, so that like in other ex-FERA companies, the foreign share-holders would continue to take all the policy-decisions but the company would now be legally counted as Indian. Thus a couple of restrictions applicable to the FERA companies would now be applicable to only two companies. There has been a demand to put all the ex-FERA companies is a separate category and not to treat them on par with the rest of the Indian companies. But under Rajiv Gandhi's leadership, such a demand has not been accepted. Self-reliance is no more a serious slogan.

Increased Rates of Profit

Under the New Drug Policy, the drugs have been recategorised as category I and II. Category I would consist of those drugs which are required for various national health-programmes; and category II would consist of 'other essential has not been published. The whole aim of this exercise is to reduce the total number of drugs under price control. Only those drugs belonging to these two categories would be under price control. The prices of the rest would be 'monitored'; but they would be out of the price control basket. Going by the list prepared by the National Drugs and Pharmaceutical Development Council (NDPDC), three years back, this list of "essential drugs" would consist of around one hundred drugs, instead of the required number of around two hundred. Today, about 360 bulk drugs are under price control; the majority of these would now join the category of decontrolled drugs.

Even those which would continue to be under price control, would fetch a higher profit-rate than hitherto. According to the Drug Price Control Order (DPCO) of 1979, category I consisted of life-saving drugs which were allowed a 40 per cent 'mark-up;' category II consisted of 'essential but not life-saving' drugs with a permissible mark-up of 55 per cent and category III consisted of 'useful drugs, new drugs' with a 100 per cent mark-up. The rest, mainly consisting largely of quite useless drugs could earn unlimited profits. The NDP has now two categories with a "Maximum Allowable Post-manufacturing Expenses" (MAPE) a new term for 'mark-up'—prescribed as 75 per cent and 100 per cent respectively for these two categories. (Readers may note that 'mark-up' or MAPE includes manufacturer's profit plus costs and profits of transport, and sale.) This hike in mark-up would cause a price-rise in life-saving and other essential drugs in these two categories by 12 per cent to 25 per cent according to the government's own admission. Many essential drugs are not going to be included in these new categories I and II and hence would be decontrolled. Their prices would increase 'as much as the market can bear'. As a result the prices of essential drugs would rise much more than this official estimate. According to the Secretary of the Indian Medical Association, which is otherwise a conservative body, the drug prices would rise by 60 to 300 per cent.

Unnecessary Price-rise

Many of the leading national dailies have refrained from criticising head-on this increase in mark-up. Many of them have called it as a 'sensible' step. If one takes the arguments of the drug industry, uncritically, this step appears sensible indeed. But this increased mark-up and consequent price-rise in unjustified on three accounts:

a) The drug industry argues that the earlier mark-up of 40 per cent and 55 per cent was 'unremunerative' This assumes that the cost-price as given by the drug industry is not fictitious. The cost calculations furnished by the industry to the Bureau of Industrial Costs and Prices (BICP) are considered as trade-secrets and are not available for scrutiny by any other public body. Let these figures be published and be verified by other experts in the field. The study quoted by industry sources to show that the earlier mark-up was not remunerative was done by the National Council of Applied Economic Research (NCEAR) but was funded by the drug industry. Let there be an independent study by a public body to determine the real costs of manufacturing. It is only then the question whether the existing mark-up is genuinely inadequate can be meaningfully discussed.

b) It is true that the wholesaler stockist claims 8 per cent of the selling price as his commission and the retailer a minimum of 11 per cent. These selling costs are in addition to transport and sales-promotion costs. This leaves comparatively limited profits for the manufacturers when the mark-up is 40 per cent (i e, when the selling price is to be upto 40 per cent higher than the manufacturing costs. This calculation, it may be noted, assumes that the manufacturing costs have not been fictitiously jacked up.) If this is the situation, the real solution in order to increase manufacturing profits is to reduce the costs and profits of distribution and marketing. The wholesaler's margin should be reduced to 3 per cent as in the case of other sectors. Secondly, the promotional expenses can be drastically reduced. Giving free samples, gifts to doctors, dinners after 'scientific seminars', etc, etc, are huge social-wastes which need to be stopped. But the Indian state is not in a position today to control the profiteering of even a section of the commercial bourgeoisie (the stockists). That is their problem. The left should ask why should the people pay the price for the timidity of the Indian state? Similarly, high-promotional expenses are "necessary" for monopoly capitalism, but the left has to ask—" why should the people pay for these necessities of monopoly forms of competition'? In case of the MNCs, these promotional expenses were as much as 33 per cent of the costs as per the data collected by the Lovraj Kumar Committee.

c) Today drugs are costly because they are available mostly in the form of drug combinations. Most of these drug combinations consist of an essential drug and one or more unnecessary or useless or even harmful ingredients. For example, popular analgesic brands like Aspro, Anacin, Powerin etc, etc, consist of aspirin as the essential ingredient and in addition one or two unnecessary ingredients. The price of aspirin is 3 to 5 paise, whereas that of these irrational brands two to four times as much! AIDAN has, therefore, demanded that all such irrational drug combinations should be banned and that only rational, essential drugs be made available under generic names only. If there is a sufficiently strong movement which makes the government accept this demand, then prices of a overwhelming majority of drugs would be drastically reduced. (Prices of single-ingredient drugs will not be reduced much.) A rise in mark-up if, and to an extent genuinely necessary, can be allowed only if this above demand is accepted. In such a case, the price of aspirin would be increased by one or two paise but since there would no more be any costlier irrational brands (Aspro, Anacin etc.) available at all, the consumer's expenses on analgesics would still be much less. This demand of AIDAN has no been accepted by the government because the movement is not strong enough.

This demand is not a socialist demand in itself since it does not question the very existence of the capitalists in the drug industry. All it says is that "you earn a reasonable rate of profit by selling really useful drugs and not a lot of junk in addition." The World Health Organisation and other such

non-socialist bodies have also been advocating the sale of only rational, essential drugs under generic names. The problem is, the people's movement, the health movement is not strong enough today to force the government to discipline and control the parasitic, antiquated interests like those of the stockists, or the monopoly-interests in the drug industry. Though monopoly capital as a whole is in the dominant position in India, a control over their reckless profiteering *in one sector* is possible even within bourgeois bounds if the people's movement is strong enough. This has been achieved to a certain extent in Bangladesh due to the combination of public pressure, historical accident and populist initiative by the government. A similar thing can happen in India also.

Delicensing and Indigenisation

According to the industry, licensing means a lot of unnecessary beaurocratic interference (which also breeds corruption) with the "freedom of enterprise". But this is an antiquated, 19th century thinking. That "free-market economy" leads to repeated small and big crises which are too painful for the people and hence inconvenient to the capitalist class as a whole and therefore, capitalism needs to be regulated at least to a certain extent has been proved in theory and in practice over and over again the world over. It is true that some of the licensing procedures and other governmental regulations are too cumbersome today and they also create another parasitic layer of administrative beaurocracy which sometimes harasses the individual capitalists or other citizens for its own corrupt interests. Thus a regulatory mechanism which has evolved historically to smoothen to a certain extent, the anarchic function of capitalism is not doing its job properly.

The solution to this is not to abolish the regulatory mechanism itself; but to simplify it, to make it more efficient and functional. But under Rajiv Gandhi's leadership, there is not even a concern for overall planning in the interests of the capitalist class as whole. The new 'modern' policy-makers have been yielding in an *ad-hoc* manner to the purely sectional interests of the Indian and foreign monopolists or sometimes to the purely sectional interests of other sections of the capitalist class. This is at the expenses of the working-masses and also at the expense of the long-term interests of the Indian capitalist class as a whole. The policy of delicensing in the drug-industry by the Rajiv-regime is a case in point.

Before the announcement of the NDP, the Rajiv regime had delicensed 82 drugs which means any company can produce any of these 82 drugs to any extent without prior permission of the government. Now according to the NDP, this policy is to be 'progressively extended'. The reasons given for this policy are: to remove unnecessary hurdles in the way of the industry, so that there will be abundant production of those drugs which are in short-supply. But in reality the consequences would be quite different:

a) Many of the essential drugs have been in short-supply today not because of the licensing system (a few exceptions apart) but because they were under price-controls. The drug industry could get a much more higher rate of profit in the production of decontrolled drugs and hence it concentrated its efforts on the production of these high-profit though mostly useless drugs. Of the 94 drugs delicensed, 75 so far (even before the announcement of the NDP) have been open for all sectors for production. But the MNCs and big companies by and large neglected their production. In the NDP, except for about a hundred drugs, all the rest would have no price-controls and hence the drug industry would continue to neglect these 100-odd priority essential drugs and would continue to concentrate on the rest. The shortages of priority essential drugs would continue so long as the non-essential, useless, irrational drugs are allowed to be produced and moreover are allowed higher-profit rates.

In case of certain essential drugs the existing capacities are today underutilised because the drug-companies have not been interested in a 40 per cent or 55 per cent mark-up. But now that the mark-up on these drugs has been increased to 75 per cent and 100 per cent, the drug-companies may now fully use their existing capacities. In the short-run therefore, there may be increased production of some of the essential drugs. This should not be interpreted as "success of the delicensing policy". In the long run, newer capacities would be developed for the decontrolled drugs more than those for the priority essential drugs.

b) Whatever limited planning that exists in capitalism requires that the planning authorities can intervene to stop/reduce or encourage the production of certain drugs or to intervene to balance the growth of different types of companies in different areas. Delicensing would mean the drug production would be entirely left to the chaotic market forces. The government would not be able to do anything about it, nor would it be able to threaten the monopoly companies with the stick of the licensing authority if these companies indulge even in brazen malpractices to fleece the consumers.

Delicensing would not be applicable to FERA and MRTP companies. But now legally there would be only two FERA companies and only a couple of Indian drug companies would be counted as MRTP companies since now the limit for inclusion in the MRTP list has been raised to Rs 100 crore by the Rajiv-regime.

The deleterious impact of delicensing can be congertly visualised since 12 drugs in March, 1983 and 82 more in June, 1985 have already been delicensed. As a result, a number of monopoly companies have registered capacities for production of many delicensed drugs in quantities which are 3 to 10 times the targets for the seventh Five Year Plan! Generally, most of these capacities are not utilised by the MNCs. Registrations are made primarily to preempt competition! For example, Duphar Interfram had 39 registrations in 1980-81; but utilised only 18 of these; in 1984, it acquired eight registrations but used none of these. The government cannot do anything about the chaos thus produced.

The ex-FERA companies would now more easily push out other companies and this would, amongst other things, push up the import-content of drug-production in India. A study of production of 8 drugs by MNCs after delicensing has shown that the import of these drugs has increased substantially. For example, Boots produced 20 tonnes of Ibuprofen and imported 4 tonnes in 1980-81, whereas by 1984-85, the imports of this drug by Boots increased to 62 tonnes but indigenous production by Boots increased to only 51 tonnes.

Delicensing would, therefore, lead to a further control by

the monopolies over the Indian drug industry and a further chaos with all the ill-effects for the people as well as for the balanced development of the Indian capitalist class as a whole.

Probably in order to stave off criticism on the forecasted increased import of drugs due to further delicensing the government has announced in the NDP, a scheme if 'indigenisation'. The NDP lays down that in cases where the import content of a product is more than 20 per cent, the drug companies would be required to submit an annual plan of how its production is going to be indigenised. This is a very loose formulation. Suppose, a foreign company unnecessarily imports, say codene, and prepares a costly, irrational cough mixture by adding a number of unnecessary ingredients to it so much so that the imported essential ingredient comes to less than 20 per cent of the total cost then, this new restriction of 'indigenisation' would not be applicable to this product. Thus vital, essential ingredients can continue to be imported in large guantities. Secondly, there is no time-limit given for 'indigenisation' nor any punishment specified if the companies do not observe in practice the plan of 'indigenisation'.

What is in fact needed, and is technically, definitely possible, given the developed technical capacity of the drug-industry in India, is more or less a complete indigenisation in say three-five years and rapid, drastic reduction in the current rising drug-imports (Rs 198 crore in 1984-85!) Sudip Chaudhury (see references) amongst others, in his detailed study, has shown that this is technically very much possible. The Indian state, because of its class-character is not able to take this step even today. On the contrary, during the last five-six years (even before the Rajiv regime), it has been forced to give more and more leeway to MNCs. The NDP is yet another example that Rajiv Gandhi's leadership has considerably accelerated this proces.

Broad banding

This is another measure to "remove the unnecessary hurdles in the growth of the industry." Broad-banding means that if a drug-company gets a permission for the production of penicillin, then now it can produce all types of penicillins and chemically related analogues like ampicillins and the like. The companies would not be required to take separate permission from the drug controller for a new formulation once the basic type has been allowed. If such broad-banding is done for single-ingredient bulk drug only, then it is a sensible step within the chaotic capitalist economy because companies can produce in the same plant, chemically related products in changing quantities depending upon orders they receive without asking for a licence each and every time. This can enable them to fully utilise the production-capacities they have built.

But the NDP allows broad-banding of formulations also. This means that if a company has a licence to produce a mixture of say three types of analgesics or vitamins, it can change their proportion or change a bit the chemical structure of one or more of its ingredients and sell the 'new' product under a new brand name. Earlier, the companies had, at least, to undergo the formality of applying and getting a permission. Now there will be a totally uncontrolled growth of all sorts of irrational drug-combinations sold under a range of newer brand-names. It would become more or less impossible to monitor the prices of the new formulations in order to check price-rise. Monitoring the quality of drugs would also be a mammoth task for the government since it is impossible to check the ingredients qualitatively and quantitatively if we have over 50-60,000 formulations.

Quality Control

The NDP seeks to make Good Manufacturing Practices a statutory requirement. This was quite an overdue step. But the problem is, there is no mention of qualitatively improving and strengthening the existing too weak, too ineffective and corrupt drug-regulatory authority. The statutory requirements would, therefore, remain on paper.

The NDP is to make a compulsory certification system for quality-control from 'recognised institutions'. This means, now there will be specified institutions for this purpose. Whether such institutions would be private or public has not been mentioned. Going by the Rajiv regime's trend towards privatisation, it is likely that privatisation will take place here also. The data with private laboratories is considered trade-secrets and generally it is impossible to get these data to find out whether a particular private company has been doing its job honestly or whether like the notorious Chemical Labs involved in the JJ Hospital death-scandal, the private laboratory is giving false reports. Though many public authorities tend to be as secretive, public laboratories can be more accountable with increased public pressure. In case of private laboratories, it is their constitutional bourgeois right to keep their trade-secrets confidential.

The government does not want to spend money on increasing the number of public laboratories upto the required number whereas it is willing to squander money on all types of useless or anti-people projects. Hence the move towards privatisation. This must be stoutly opposed. At the same time, as a measure of rational utilisation of existing resources, public bodies like laboratories in research-institutions, universities, etc, can be entrusted to a certain extent, this task by fortifying these facility-centres with the needed extra equipments and personnel. This would obviate to a certain extent the need to build new facility-centres from scratch. Whether the existing system can do this is a moot point even if socially, it is quite a viable propositon.

Medical Issues

Health and science groups in India have identified the following key-issues from a medical aspect as part of a rational drug policy; none of which find a place in the NDP.

i) Preparation of a priority essential drug-list and a comprehensive rational drug list for India. Production of drugs to take place in accordance with only these lists and no other.

ii) To assess quantitatively the drug needs of the Indian people on the basis of a study of prevalence of the disease-pattern in the country and to plan the production accordingly.

iii) To completely and immediately ban all the irrational and hazardous drugs. Only drugs as specified in (i) to be allowed.

iv) Complete abolition of brand-names and replacing them

with generic names, with the company's name in the brackets; for example, "Penicillin-V (Alembic)".

v) Stopping the 'disinformation' of doctors and consumers by drug companies. Continous compulsory reeducation of doctors and relevant education of consumers by state medical authorities.

vi) Strict check on the unethical marketing practices by the drug companies; a ban on incentive-schemes and on giving samples and gifts to doctors by drug companies.

vii) Adequate supply of drugs free of charge to poor people through the government set up. Rational utilisation of the existing budget and increasing it rapidly to the adequate level.

vii) To stop the continuing colonial heritage of step-motherly treatment being given to the non-allopathic systems of medicine; to encourage research in these systems with financial and other support. At the same time to disallow the commercial production of any drug by any company unless it is accepted as scientifically proved (effective and safe) by appropriate bodies. Encouragement to ayurveda does not meant that Richardson-Hindustan be allowed to avoid taxation or to get other concessions by naming its Vicks Vaporub as herbal medicine! To enact that medical practitioners would use only those medicines or therapies in which they have been adequately trained by recognised institutions.

The NDP talks about only the standardisation of non-allopathic drugs and preparation of standard formulary for non-allopathic systems of medicine. There is no serious research policy nor any attempt to curb production of irrational (may be hazardous also) medicines under the name of ayurveda of the misuse of these medicines.

ix) All medical research on human beings must be statutorily required to confirm to the 1975 Helsinki (Mark II) Declaration. This should be strictly followed in case of contraceptive research also.

None of these medical demands have been accepted. One may conclude that the NDP is only a pricing and 'liberalisation policy' with no concern for rationalty or people's health needs. The foregoing account shows that as an industrial policy also, it is clearly reactionary and anti-people.

Selected reference material

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3 *Issues involved in Drug Policy*, Prepared by Pondicherry Science Forum, pp 56, Price Rs 6.50, Chennai Books, 6, Thayar Sahib Street, II Lane, Madras 600 022.

4 *'Manufacturing Drugs without TNCs'*, Sudip Chaudhury, *EPW*, Vol XIX, Nos 31-33, August 1984.

5 S Singh, *Multinational Corporations and Indian Drug Industry*, Criterion Publications 1985.