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FOR A RATIONAL SCIENTIFIC HEALTH-ORIENTED NATIONAL DRUG POLICY

DRUG ACTION FORUM, W.B.
S/3/5, Srabani, Sector-III, Salt Lake,
Calcutta : 700 091, India

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Several declarations have been made by responsible bodies, e.g., Hathi Committee, WHO, Non-aligned Summit Conference, etc. providing objectives and guidelines for a rational drug policy relevant for the countries like India. Concerned persons and organisations have been campaigning for a rational and scientific drug policy oriented towards the protection and maintenance of health of the people, replacing the present profit oriented drug market. For various reasons, the Government of India is going to adopt a new national drug policy which, according to available information, neglects the health approach and provides for more concessions to the industry and profit. It is, therefore, necessary to identify the basic elements of a health oriented drug policy and to do that one needs to be acquainted with the prevailing drug situation of the country.

WHAT IS A DRUG ?

According to medical science, a substance is called a drug when it is so recognised in the text books of Pharmacology and Medicine and is recommended for some ailments. The number of drugs actually does not exceed 400, but in India the number of licensed drugs for sale in the market is more than 60,000. The apparently unbelievable situation stems from a number of reasons :

1. A single drug is allowed to be marketed not by its Generic name (universally accepted scientific name), but by a different ridiculous name (Brand name) by each company.

2. A large number of substances having no scientific basis at all, e.g., tonics, expectorants, drugs to increase vitality, growth promoters, etc. have been allowed to be marketed as drugs. These 'drugs' enjoy enormous profit margin and a large market created by false propaganda.

3. Combination Drugs: By irrational and unscientific combination of two or more drugs of both scientific and unscientific nature, a large number of 'new drugs' have been created. These constitute the largest number and enjoy the largest market and high profit margin.

4. Herbal Drugs: In the name of Ayurved, ancient herbal remedy and indigenous medicine, a large number of drugs have been created and no authentic scientific or experimental information is available regarding them. This uncontrolled unscientific practice draws enormous profit and is a fast growing business.

5. Distorted use of scientific drugs: A good number of scientific drugs are recommended by high pressure sales technique for ailments against which these are useless. In this way, often essential drugs are wasted. For example, Streptomycin, a valuable and necessary drug against tuberculosis which, though in short supply, is wasted by permitting its use in combination with Penicillin for other bacterial diseases and

with Chloramphenicol for diarrhoea: both these practices are not only against the principles of medical science but often harmful too.

SHORTAGE OF VITAL DRUGS

Why such unscientific practice prevails in such a vital matter involving life and death of millions ? Because of profit and more profit which has now become the sole guiding force of all social and economic enterprises. According to the Drug Price Control Order, 1979, profit margin for essential and life saving drugs is allowed in the range of 40% to 55% while in case of non-essential, unscientific and useless 'drugs', the profit margin is from 100% to limitless. That is why the drug companies engage most of their production capacity in producing non essentials and neglect low profit essential drugs. Anti- TB, anti-leprosy and anti-blindness drugs, though very cheap, are always in perpetual shortage while tonics, cough syrups, gripe water, digestives, etc. are produced in such enormous quantity that crores of rupees have to be spent in propaganda, incentive and commission to sell these products. Even in case of life saving drugs the tendency is towards larger profit. For example, because of low profit, no company is interested to manufacture the cheapest anti-TB drug INH but everyone is eager to import the costliest but high profit anti-TB drug Rifampicin which is never in short supply in the market.

HARMFUL PRACTICE

A large number of drugs which are banned in different countries because of negative benefit/risk ratio, are being

manufactured and sold here under false pretenses. Chloramphenicol-Streptomycin combination, Clioquinol, Anabolic steroid, high dose Oestrogen-Progestin combination, Analgin, Oxyphenbutazone, etc. are some of the examples. It is inexplicable that while Ciba Geigy, the largest manufacturer of Oxyphenbutazone, has stopped its production because it is harmful, many other companies are allowed to produce the same in India. More inexplicable is the fact that while Drug Controller of India has prohibited the use of this drug except only for a couple of adult diseases, syrup preparations of this drug for children are, at the same time, allowed to be marketed. It is difficult to find a better example of anarchy.

THE PRICE QUESTION

Arbitrary pricing is a routine practice in India. Tinidazole is sold by different companies at different prices, e.g., Biddle Sawyer (Rs.6.40), John Wyeth (Rs.7.80), Unichem (Rs.8.90), Sarabhai (Rs.9.00) etc. Drugs of similar composition are sold at different prices, e.g. Corbutyl (Rs.53.00) Norgesic (Rs.66.00), Proxyvon (Rs.75.00). There are innumerable examples of such arbitrary pricing. The system of selling a drug in different ridiculous brand names is the chief cause of unreasonable high price of drugs. To sell its own brand in competition with a host of others, a company has to spend a lot for promotion, publicity, incentive, commission, fancy packing, addition of irrational combination, bribery etc. All these expenditures are added to the ultimate price of the drug. The multinational companies on an average spend 33% of their total ex-

penditure on drug promotion and overhead while allocate a meagre 0.8% to research and development.

QUALITY CONTROL

The importance of strict quality control of drugs cannot be overemphasized. The state of inadequacy of our drug control authorities (DCA) first disclosed by the Hathi Committee in 1975, has not improved. To deal with 8000 manufacturers, 60,000 drug items and innumerable drug shops we have only about 500 inspectors and 5 testing laboratories, all not so well equipped. Only a sample survey (1980) has revealed that 20% of drugs in the market are spurious and substandard; of the 218 samples of big multinational companies 135 were found to be substandard. Moreover, there is no mechanism or facility in the country to monitor and document adverse reactions to drugs.

The most important fact which has so long escaped notice of almost all concerned is that the DCA have no facility or capability to test and verify whether a substance has the properties of a safe drug for human beings. That is why, whenever a company applies for a drug license for a new substance alongwith the statements of efficacy, the DCA has to believe these statements and issue license.

DRUG INFORMATION AND MARKETING

There is no control over the propaganda or promotion of drugs. That is why the companies propagate with impunity, concocted false claims, untruths and half truths in publicising the efficacy of their drugs. The doctors and the consumers rely on these information. There are a number of reasons and evidence that many multinational companies are forced to ad-

vertise only scientifically established facts in the developed countries because of punitive regulations while they propagate exaggerated, unscientific and imaginary benefits for the same drugs in India. Here, there is no system of dissemination of scientific drug information by the Government to the medical profession and health workers.

Control over the marketing of drugs is also practically non existent. One can purchase any number of dangerous drug over the counter without prescription of a doctor. It is an open secret that in the business centres of bulk transaction, there are separate parallel counters of standard and substandard drugs.

ELEMENTS OF A RATIONAL SCIENTIFIC DRUG POLICY

It is a crime to deprive a dying person of the opportunity to save his/her life and prevent avoidable death or disability with the help of life saving and essential drugs. In India such deprivation appears to be routine. It is, therefore, imperative to draw the attention of all concerned for an urgent action in the matter in order to absolve the nation of this criminal conduct. We must adopt and implement a rational scientific drug policy to serve the people in need. From the foregoing the following basic elements of such a policy emenge :

1. To allow manufacture and sale of only those drugs which are recommended by the text books of Pharmacology and Medicine.

2. To prepare a list of "Essential Drugs" on the basis of the recommendations of WHO, to achieve immediate self sufficiency and eventual self reliance in the Essential Drugs and to ensure their availability to all persons in need, particularly those who lack the purchasing power.

3. To allow marketing of drugs only in their generic names.

4. To ensure strict quality control.

5. To control propaganda of drugs within the tenets of scientifically established facts; to provide for dissemination of all scientific drug information to the medical profession and health workers and through appropriate data in the drug package in the relevant regional languages for the consumers.

* * * * * * *

Drug Policy Old & New

India does not have any comprehensive drug policy in the true sense of the term. What passes for drug policy in our country is infact a drug pricing policy which is formulated by the Ministry of Chemicals & Fertilisers (now the Ministry of Industry) not by the Health Ministry. The existing Drug Policy was announced in 1978 and this was followed by the promulgation of Drug Prices Control Order in 1979. By this order Govt. has categorised all the drugs into four categories viz. I, II, III and IV depending on the essentiality of the drugs and fixed a limit to the profit margins (Mark up), which is 40, 50 & 100 percent respectively for the first three categories while Govt.allowed unlimited profit margin for drugs belonging to Category IV (decontrolled). The idea perhaps was that drugs belonging to Categories I & II (Essential & life saving drugs) would not fetch desired profit for the drug manufacturers which they will make good by producing drugs belonging to Category IV. The total number of drugs brought underCategories I to III was 347 leaving the vast majority out side the price control basket. Drug manufacturers were not ready to be under any control whatever minimum it might be. They fought back and tried to foil the DPCO in several ways. Several (multinational) companies cut down the production of essential & life saving drugs (Category I & II) and stepped up the production of decontrolled drugs (Category IV).

Table I

Drug	Lisenced capacity	Actual production (Metric Tonnes) 1980	1981	1982	1983
PAS	110	13.5	13.78	5.7	Nil
INH	80	73.77	54.00	71.5	Nil
Protinex	110	254.86	252.15	278.59	not known

Data relate to Pfizer, a multinational company.

Through dubious means they have increased the price of almost all drugs including essential ones -

Table II

Name of product Packing (Manufacturer)	Price-June '81 (a)	Price June '84 (b)	percent Rise (c)	price Sept '85	Percent rise from (a)
	Rs. P.	Rs. P.	(c)	Rs. P.	(a)
1. Driston (Maneesh)	4—25	6—90	62	8—12	97
2. Otrivin (Ciba)	4—75	6—38	34	8—00	68
3. Anaconyl (Ciba)	1—28	2—33	82	2—50	95
4. Digiplex-170 m. (Rallis)	5—35	12—65	98	14—84	177
5. Vitazyme-110ml (East India)	4—60	8—14	77	9—50	107
6. Takazyme (P&D)	4—40	8—92	103	11—22	155
7. Dexorange-200ml (Franco-Indian)	10—29	14—50	41	19—00	85
8. Hepatoglobin-200ml (Raptakos)	11—14	19—12	72	20—08	80
9. Protinules-100g (Alembic)	9—86	13—22	34	13—91	41
10. Protinex-225g (Pfizer)	14—50	21—72	50	21—72	50
11. Sys-300g (AFD)	15—02	16—71	73	28—71	91
12. Durabolin-25 mg. ml (Organon)	7—28	10—54	45	12—10	66
13. Sustanon-1ml (Organon)	20—07	31—21 (10 tab)	56	35—80 (10 tab)	79
14. Lynoral (20 Tab) (Organon)	1—06	3—20	515	3—75	614
15. Menstrogen (20 tabs) (Organon)	6—00 (20 tab)	4—88 (10 tabs)	56	6—00 (10 tab)	100
16. Mixogen (20 tabs)	3—55 (20 tab)	4—53 (10 tab)	155	5—20	192
17. Aquaviron-B 12-1 ml (Nicholas)	2—41	5—50	128	6—04	151
18. Calin 500 (Glaxo)	1—86	3—00	53	3—33	70
19. Sukcee (IDPL)	2—02	3—26	61	4—60	128
20. Stemetil (M&B)	0—88	2—32	164	3—68	307

Source : (from MIMS '81) (Actual price printed on pack) (Actual price printed on back)

A couple of years after the promulgation of the DPCO, (1979) the apex bodies of the drug manufacturers viz. OPPI (Organisation of Pharmaceutical Producers of India, a multinational lobby) and IDMA(Indian Drug Manufacturers Association, organisation of Indian large houses) started pressurising the Govt. on the plea that their business has become unremunerative. They could collect and compile favourable data through NCAER (National Council of Applied Economic Research), a private organisation and submitted them to National Drug and Pharmaceutical Development Council (NDPDC), a body having several represention from the industry and the chairman of the said council is the managing director of a drug company. Naturally, NDPDC reacted sympathetically and soon constituted three working groups to examine the situation. Recommendations of the Working Committees were considered by a steering committee who failed to reach any unanimity. The matter (draft new drug policy) was then presented to the Parliamentary Consultative Committee (PCC) on drugs and pharmaceuticals. PCC differed with the views of the steering committee. In the mean time the said PCC has been disolved and a new committee has been set up which does not include any of member of the former committee. Following Tables will show that the claim that 'drug business' has become non-remunerative is not true.

Table-III

WHO SAYS THE DRUG COMPANIES ARE INCURRING LOSSES?
COMPANY-WISE FINANCIAL DATA WITH PROFITABILITY RATIOS FOR SELECTED 30 PHARAMACEUTICAL COMPANIES

Name of Company	Financial year	Total assets	Net Seles	Gross profit	% retun on total capital employed
1. Glaxo Lab.	June '83	93.75	136.17	14.28	14.8
2. Hind. Ciba Geigy	Dec. '83	62.04	101.18	10.89	14.12
3. Hoechst(I)	Dec. '83	49.70	80.67	9.00	28.25
4. Sandoz (I)	Dec. '83	41.81	63.17	6.56	11.23
5. Alembic	Dec. '83	33.08	56.26	5.99	15.64
6. Pfizer	Nov. '83	37.50	52.08	5.99	15.64
7. May& Baker	Dec. '83	31.29	41.30	5.98	6.67
8. Ranbaxy	Dec. '83	37.53	37.06	3.83	13.58
9. Boots India	Dec. '83	15.18	33.69	3.48	14.21
10. Burroughs	Aug. '83	29.05	32.68	4.55	15.44
11. German Remedies	Dec. '83	20.99	31.77	4.39	22.13
12. Cynamid(I)	Nov. '83	17.76	27.55	4.95	15.55
13. Parke-Davis	Nov. '83	8.85	26.08	2.51	13.14
14. Warner Hindustan	Nov. '83	8.55	25.45	2.53	15.55
15. E.Merck (I)	Dec. '83	18.52	23.18	2.12	19.38
16. Richardson Hind.	June '83	10.18	23.30	3.15	20.21
17. Roche	Dec. '83	15.30	22.30	4.50	28.34
18. CIPLA	Oct. '83	13.14	20.54	1.44	5.42
19. Unichem Lab.	Sep. '83	10.06	19.56	2.04	12.09
20. Abbott Lab.	Nov. '83	7.53	15.28	1.80	14.09
21. Searle (I)	Dec. '83	10.35	13.52	0.92	12.07
22. Boehringer	Apr. '83	6.53	11.35	3.26	29.40
23. Duphar-Int	Dec. '83	7.01	12.49	-0.47	21.25
24. Nicholas Lab	June '83	9.84	11.31	1.29	12.20
25. Fulford (I)	Dec. '83	5.88	9.42	0.64	22.18
26. Jayant Vitamin	June '83	14.81	8.81	1.08	20.44
27. Amrutanjan	Mar. '83	4.25		0.50	21.59
28. J.L. Morson	Dec. '83	4.92	8.52	1.01	17.93
29. Chemo Pharma	June '83	3.09	0.12	0.05	7.93
30. Zandu Pharma	Mar. '83	4.47	4.94	0.50	16.27

CHEMICAL WEEKLY, MARCH 5, 1985

WHO SAYS THE DRUG COMPANIES ARE INCURRING LOSSES?

Table-IV

CHEMICAL WEEKLY & TIMES OF INDIA March 5, 1985
Feb. 12, 1986

BOOK VALUE AND PRICE SHARE OF PHARMACEUTICALS

Sr. No.	Name	31-12-81	31-3-82	31-12-82	31-3-83	31-12-83	31-3-84	31-12-84	12-2-86
1.	Glaxo	20.50	22.00	31.00	21.50	24.00	24.25	24.25	83.00
2.	Hindustan					277.50	285.00	262.50	
3.	Hoechst							375.00	1000.00
4.	Sandoz	28.00	27.00	41.00	35.00	42.00	44.00	32.50	87.00
5.	Alembic	70.00	91.00	139.00	141.00	122.00	107.50	85.00	145.00
6.	Pfizer	24.00	23.50	36.50	31.00	37.25	38.50	40.00	124.00
7.	M&B	15.00	15.75	25.00	21.50	30.00	30.50	30.50	71.00
8.	Ranbaxy	19.50	26.50	37.50	36.50	49.00	44.00	36.50	155.00
9.	Boots	23.00	24.00	39.00	33.00	56.00	67.00	46.00	200.00
10.	Burroughs							58.00	190.00
11.	German R.	26.50	29.50	35.50	31.00	32.75	36.25	36.00	82.50
12.	Cynamid	29.00	28.00	38.00	26.00	34.40	41.00	38.50	95.00
13.	Parke-Davis			29.50	23.50	30.00	33.00	29.50	66.00
14.	Warner Hind	21.50	22.00	31.00	28.00	37.00	36.00	38.00	110.00
15.	E. Merck		16.25	33.00	28.50	31.00	34.00	34.50	100.00
16.	Richardson	24.00	22.50	39.25	38.00	64.00		63.00	
17.	Roche			N.A.				19.00	
18.	CIPILA								
19.	Unichem	145.00	145.00	140.00	145.00	180.00	167.00		
20.	Abbott			61.00	22.00	24.00	27.50	27.00	53.00
21.	Searle	42.00	35.00	68.00	59.00	47.00	44.00	80.00	407.50
22.	Bochringer	16.00	12.75	18.50	14.50	18.00	17.75	11.75	98.00
23.	Duphar	30.00	20.00	31.00	25.00	49.00	41.00	30.00	
24.	Nicholas							19.50	
25.	Fulford		21.75	34.00	30.00	47.00	56.00	76.50	
26.	Jayant	6.50	5.00	9.00	6.25	11.50	11.50	10.00	
27.	Amrutanjan	41.50	40.00	36.00	40.50	46.00	45.00		
28.	J.L.Morrison	13.50	13.00	14.50	13.25	14.00	14.00	17.00	
29.	Chemo-Pharma	32.00	18.00	22.50	22.50	22.50		22.50	
30.	Zandu	100.00	100.00	100.00	147.50	147.50	200.00		
31.	Bayer	-	-	-	-	-	-	-	680.00
32.	ESKEY	-	-	-	-	-	-	-	210.00
33.	CIBA	-	-	-	-	-	-	-	600.00

BUSINESS UNAFFECTED
INDUSTRY KNOWS HOW TO GROW

Table-V

GROWTH OF THE FIRST TWENTY RANKING PHARMACEUTICAL COMPANIES

	Company	Country of Origin	Sales in 1979 in Rs. Crores	Sales in 1984 in Rs. Crores	Growth %
1.	Glaxo	U.K.	35.10	54.55	55.41
2.	Sarabhai	US Colaboration	33.59	51.34	52.84
3.	Pfizer	U.S.A.	28.93	40.65	40.51
4.	Hoechest	F.R.G.	17.45	33.16	90.03
5.	Alembic		21.66	32.09	48.15
6.	Cadila		9.87	28.88	192.60
7.	Burroughs Wellcome	U.K.	13.51	26.74	97.92
8.	Boots	U.K.	12.14	25.67	111.45
9.	Ranbaxy		8.75	23.53	168.91
10.	German Remedies	F.R.G.	10.53	19.25	82.81
11.	Parke Devis	U.S.A.	11.85	18.90	59.50
12.	S.G. Chemicals	Swiss Colaboration	11.69	17.90	53.12
13.	May & Baker	France	9.89	17.50	77.30
14.	SKF(ESKAY)	U.S.A.	8.23	17.15	108.38
15.	Raptakos-Brett		10.06	17.10	69.98
16.	E.Marck	F.R.G.	8.50	16.65	95.88
17.	IDPL		9.10	16.60	82.41
18.	CIPLA		4.54	15.75	246.91
19.	Warner	U.S.A.	9.72	15.50	59.57
20.	Unichem		9.76	15.35	57.27

Source: ORG, MAT May '84.

PRICE HIKE IN DRUGS

Name of the Drug	Theraputic Group	Company	Max. Retail Price in '74 Rs.	Max. Retail Price in '86,Rs.	% of Increase
Streptomex	Anti TB	Pfizer	Each Vial 0.70	2.77	296
Sodium PAS	Anti TB	Pfizer	100GM 5.62	15.68	180
Protinex	Neutrient	Pfizer	115GM 5.20	13.37	157
Insulin CEG	Antidiabetic	Boots	10m Amp. 5.01	11.10	121
Cadiquin	Antimalarial	Cadila	Each Tab.0.17	0.28	64
Dexorange	Blood Tonic	Francho Indian	280ml. 7.50	16.50	120
Panzynorm	Enzyme	German Remidies	Each Tab.0.20	0.68	240
Triredisal	Vitamin B_1 B_6 B_{12}	Merind	Each Tab.0.14	0.32	129
Raehlor	Chloramphemicol	Sarabhai	Each Cap.0.36	0.57	171
Calpol	Paraeetamol	Burroughs	Each Tab.0.07	0.20	186

The new drug policy document has been kept secret. Reports published in the press (Appendix I, II & III) definitely show that the new drug policy if passed in its present form will surely affect the consumers adversely. Some of the outstanding changes proposed in the new drug policy are -

1. The number of drugs under price control has been reduced from 347 to only 65.
2. The profit margin has been elevated from 40 - 55% to about 75 to 80%.

The drug policy both the existing as well as the new one are not drug policies at all because -

1. These are not based on the health needs of the people.
2. These have been formulated by the Chemicals & Fertilisers/ Industry Ministry and not by the Health Ministry.
3. These have only considered the health of the drug industry, their production and pricing and not the health of the people.
4. These policies are silent about the fates of several thousands of 'non-drugs' and harmful drugs which have been banned abroad but continue to be produced and marketed in our country.
5. No discussion about quality control of drugs.
6. These policies have only discussed the production of drugs and remained completely silent about the availability of drugs to indigent people who do not have purchasing power.

7. No discussion about the supply of unbiased information about drugs to the doctors as well as the consumes.

8. The policies do not mention about the fate of drug companies who violet the policies and orders.

9. Drug policies also do not mention the ways and means by which the leadership role of the public sector, as envisaged by the Hathi Committee (1975) can be ensured and the country can be self sufficient in drugs.

10. The new drug policy is going to introduce a new item viz. broad banding which will open the flood gates of irrational drug production further.

Appendix-I

Farce of Drug Policy

IT was in August 1984 that the Steering Committee of the National Drug and Pharmaceuticals Development Council (NDPDC) published its report which was supposed to form the basis of a new drug policy. It provoked much debate and sharp criticism from both the industry and health activists and consumer groups for very different reasons. The announcement of the new drug policy has been imminent throughout last year and the government has issued periodic statements about 'finishing touches' being given to it. The latest indications are that the policy is now ready and will be tabled in the current session of Parliament.

All that has been forthcoming from the ministry so far indicates that the drug policy is directed solely towards promoting the growth of the pharmaceutical industry and facilitating a doubling of its capacity in the next five years; that there is likely to be an all-round increase in drug prices; and that the price control basket will further shrink. The minister has also repeatedly stated that companies with less than 40 per cent foreign equity will be treated on par with wholly Indian companies.

As of now there is absolutely no sign that the drug policy has even considered such issues as the preparation of an essential drugs list, the need to curb the vast array of unnecessary formulations, the continuing availability of harmful, irrational combination drugs many of which have been earlier banned by a government order. Nor do the policy-makers appear to have taken cognisance of the Hathi Committee's recommendations on introducing the use of generic names instead of brand names. Issues such as the tightening of procedures for drug licensing, monitoring and quality control too have apparently received scant attention. It is clear that the well-documented and substantiated criticisms of health activists and concerned consumers and doctors on the Steering Committee's report have fallen on deaf ears. On the other hand, the OPPI and PAMDAL have been issuing pleas for a "total industrial approach" to drug policy. Quite clearly the drug industry lobby has once again proved effective.

Organisations like the All India Drug Action Network (AIDAN), a forum of doctors and health activists, have consistently pointed out the importance of drawing up a need-based essential drugs list based on the incidence and prevalence of major diseases. The WHO has since 1977 been promoting the idea of an essential drugs list based on its own list of 200 drugs. The Hathi Committee had drawn up a list of 117 drugs. Various groups in India have suggested even shorter lists for our needs. The fact that the Indian pharmaceutical sector produces 40,000 to 60,000 formulations, most of which are superfluous, some even harmful, has been underscored several times. In fact even the Minister for Health has recently stressed the relevance of an essential drugs list. The government itself has drawn up a list of 200 drugs for the Central Government Health Scheme. The minister is also convinced that in the interest of the consumer the number of formulations should be curtailed.

The Ministry of Chemicals and Fertilisers, which has the sole authority over the drug industry, has, however, completely ignored all of these considerations. In fact, it has cited the large number of drugs marketed and the consequent difficulties in imposing the Drug Price Control Order (DPCO), 1978 as the justification for its new pricing policy. In other words, instead of streamlining the process of implementing price control by reducing the plethora of products, it has rationalised their manufacture and sale by restructuring the pricing policy. Moreover, the absurdity of encouraging the growth of the industry without stipulating changes in its skewed pattern of production appears to have escaped notice altogether.

The Seventh Plan's projected requirement of bulk drugs and formulations in 1980-90 is Rs 1,033 crore and Rs 3,775 crore, respectively. It is well known that these projections are based on current sales rather than on disease patterns and their incidence rates. Most of the large drug companies have well-established sales and promotion networks which are capable of selling the most irrelevant drugs in large quantities. In the absence of consumer education and awareness, if no controls are introduced on the number of useless formulations, the pattern of production in the drug industry is likely to rapidly become more irrational in future than it already is.

The Health Minister's recent statements also bring into focus another aspect of the drugs picture that has long worried health activists. Since the drug industry does not come under the purview of the Health Ministry, the latter has no say in such matters as pattern of production, requirement of drugs or even quality control. For instance, there are only some 600 drug inspectors for the 6,000 odd manufacturing units and thousands of sales outlets. Only two states have fully equipped testing laboratories. No new plans have been mooted to remedy this situation. Given the tremendous influence wielded by the drug industry it is not surprising that the drug policy's main concerns are for the health of the industry and not for the health of the people. Another vital and urgent measure which would have ensured quality drugs at affordable prices would have been the mandatory use of generic names and a gradual abolition of brand names. Again, because of the ministry's tilted perspective towards industry and its consequent preoccupation with price structures it has ignored other comprehensive measures which would have supported the implementation of any rational pricing policy.

If the indications are right and if these are really some of the main features of the drug policy, its announcement would be almost irrelevant to most people but for the fact that the last year has seen a growing consumer awareness on drug issues. The tardiness of the government in introducing the new policy may have been the emergence of a counter-lobby to the drug industry and a growing concern among people about the high prices of drugs, spurious formulations, non-availability of essential, life-saving products and promotion of medicines banned in many countries. The new drug policy may thus be due for a stormy reception.

□ EPW, 8-15.3.86.

Appendix-II

Pharmaceutical Industry

Not By Price Control

A Correspondent writes:

THE pharmaceutical industry provides a curious blend of many paradoxes. The industry has been subjected for nearly two decades to an increasingly stringent system of price controls, currently covering about four-fifths of its production of drugs and formulations, but the impression is still widespread that the prices of medicines are on the very high side. The industry has all along been complaining about uneconomic pricing but its growth rate compares quite favourably with that of most other major industries. Despite its apparently impressive overall growth rate of nearly 15 per cent a year, the per capita availability of medicines works out to only around Rs 30 a year—the value of formulations is reckoned at Rs 1,660 crore—and the average for the rural areas is less than Rs 10.

The main objectives of the government's drug policy—production of medicines for the masses, particularly life-saving medicines and those required for the national health scheme, and ensuring quality and fair prices—are unexceptionable. But in an attempt to reconcile the conflicting interests of different sectors into which the industry is divided, the policy-mix the government has evolved over the years has done considerable harm to the cause it seeks to promote. Life-saving and essential drugs continue to be in short supply and that again not for lack of capacity but due to uneconomic prices. Or so the industry claims. In any case, one can scarcely blame the industry for concentrating its attention on the production of less essential medicines which are more profitable.

Ironically enough, the industry which produces drugs and formulations for the health and life of the people is itself sick. This, however, is scarcely surprising. The whole thrust of official action has been to promote objectives which have no relation to efficiency. Public sector firms have been promoted, protected and subsidised but they command little reputation for efficiency. Foreign companies are tightly contained and even those which have reduced their foreign shareholding to 40 per cent are discriminated against, supposedly in the interest of the wholly Indian companies. Large Indian companies are controlled by MRTP provisions. The small-scale sector enjoys several benefits, resulting in proliferation of manufacturers and multiplicity of formulations without effective monitoring of quality. Growth and innovation have been sacrificed in favour of supposed short-term social gains which have not materialised.

The present plight of the drug industry is attributable largely to the government's pricing policy which has resulted in continuous erosion of its profitability. Unsatisfactory nature of initial mark-ups apart, subsequent cost escalations without corresponding price adjustments have sharply eroded earning levels well below those prescribed by the government. New Delhi has been unable to resolve the conflict in regard to correct balance in pricing, between ensuring that benefits of competition are passed on to consumers in the form of lower prices while preserving incentives for further investment in production and innovation. What the government has tried to do is to place its priority on bringing down the cost of medicines, but not promoting vigorous competition and not by paying due regard to the returns required by manufacturers.

Unquestionably, poor countries need good quality drugs at the lowest possible cost. But this laudable objective cannot be achieved on an enduring basis without continuous growth of the industry and innovation which in turn call for adequate returns to manufacturers and innovators. The findings of an NCAER study released last year bring out the various shortcomings in the government's pricing policy. The mark-ups allowed in respect of categories I and II drugs—40 per cent and 55 per cent, respectively—have been well below the break-even point of 63/64 per cent and those in respect of category III drugs render production barely remunerative. This explains the serious underutilisation of capacity in respect of life saving and essential drugs and their consequent shortages.

New Delhi is by no means unaware of the industry's declining fortunes. Three working groups, fully representative of all interests, were appointed by the National Drugs and Pharmaceuticals Development Council last year to

study in detail the various aspects of the existing drug policy, the need for review of the policy and to recommend changes wherever necessary. Their reports were later examined in depth by the steering committee which submitted its report in August last.

The steering committee has made a number of recommendations covering almost every important aspect of the drug industry. It has suggested that price control should have a lesser span than at present. The committee has identified 95 drugs to be known as priority drugs instead of life saving and essential drugs. Only these drugs with an estimated coverage of anywhere between 50 per cent and 68 per cent of the drugs currently listed in categories I, II and III, are to be brought under price control. Views on the mark-ups vary from 65-125 per cent and a common mark-up of 75/80 per cent. The final decision has been left entirely to the government. All the drugs/formulations outside the 95 priority drugs are to be excluded from the purview of price control. The committee has suggested that the restrictions on licensing and production should be done away with and that each manufacturer should be compelled to produce 20 per cent priority drugs.

Industry's reaction to the steering committee's recommendations is mixed one. The industry's feeling is that the proposed switch-over from the three-tier to two-tier structure, welcome as it is, is unlikely to bring about any significant improvement in its fortunes. The priority drugs cover almost two-thirds of the total production and the common mark-up suggested is 75/80 per cent. Under the existing policy, almost half of the total production comes under the 60-100 per cent mark-up area. Besides, quite a good deal will depend on how the government implements the recommendations in regard to removal of curbs on licensing and production.

The industry is looking forward to the announcement of new drug policy embodying the various recommendations of the steering committee. The view is widely shared that going by the mark-ups indicated in the committee's report, prospects of a major breakthrough in production of priority drugs cannot be rated high. All that is reasonably certain is that drugs will become costlier and the rise in prices could well be quite sharp in the case of medicines exempted from the purview of control. But there is no getting away from the harsh fact that drug prices can be held in check only by promoting vigorous competition through increased production which in turn calls for adequate returns to manufacturers and innovators.

□ EPW, 24.11.84.

Appendix-III

Drug policy

THE forthcoming national drug policy is likely to prove a bitter disappointment to consumers unless the Government considers seriously, even at this stage, some of the suggestions made by consumer and health activists. The Government envisages a drug policy purely in terms of pricing and production and has therefore only consulted the drug industry. The consumers' voice has been entirely forgotten. Yet in a country like India, with an inadequate health care system, the issues raised by consumer activists, such as the quality of drugs, the shortage of inexpensive essential drugs, the excessive marketing and promotion of irrational drug combinations which are useless and often harmful, and the availability over the counter of drugs banned in many countries, are far more relevant than just profits and pricing.

Although a central issue in the debate on drug policy has been the share of the market held by the multinationals and indigenous drug companies respectively, the more relevant fact is that both sections of the drug industry are guilty of paying little heed to consumer interests. While the more profitable non-essential formulations such as tonics and restoratives are promoted and produced by them in ever-increasing quantities, the country's 10 million TB patients are hard put to find adequate supplies of simple drugs and an estimated 30,000 children go blind every year because of the lack of Vitamin A, the production of which has actually declined over the years. Even of this, a substantial percentage is diverted to multivitamin formulations, a favourite of an overdosed urban populace.

The Government has yet to heed the suggestions of the Hathi Committee, made more than a decade ago, that brand names be disallowed and that only generic names be used. The Committee had also drawn up a list of 116 essential drugs that should be produced in adequate quantities to meet the needs of the people. A couple of years later the World Health Organisation (WHO) came up with a list of 200 essential drugs and advised developing countries particularly to draw up such lists and adopt a rational drug policy instead of wasting up to 20 to 30 per cent of their already meagre health budgets on importing expensive non-essential drugs. In 1982 Bangladesh adopted a rational drug policy which allows the production of only 150 essential drugs and their marketing under generic names. These have replaced over 4,000 formulations that were flooding the market. This is an example the Indian Government would do well to study. Non-availability of essential drugs and vaccines has crippled efforts made by the Government and voluntary agencies to reach health care to the poor in the villages. A rational drug policy is the very minimal contribution the Government can make towards the goal of achieving health for all by 2000 AD.

□INDIAN EXPRESS, NEW DELHI, Monday, March 17, 1986

ALL INDIA DRUG ACTION NETWORK
C-14, Community Centre, S.D.A

New Delhi, March 21, 1986.

ALL INDIA DRUG ACTION NETWORK had discussion on 20.3.1986 in Delhi with several MPs from different political parties including - Shri Balwant Singh Ramoowalia, Shri Teja Singh, Shri Suresh Kurup, Shri Unni Krishnan, Shri Vishvjit Prithvijit Singh, Shri Mool Chand Daga, Shri Abdul Rashid Kabuli, Prof. Saif-un-din Soz, Dr. V.Venkatesh, Shri Piyus Tirakey, Shri Chinta Mohan - regarding the need for a rational drug policy..

The National Drug Policy must be integrated with the National Health Policy from the very planning stage and not be limited to licensing and pricing policy.

After the discussion on the need for a Rational Drug Policy, following statement was made :

STATEMENT

This meeting of the representative of the political parties states:

THAT the National Drug Policy (NDP) is essentially meant for the well being of the people and as such it should be open for public discussion and debate before it is adopted by the Parliament.

THAT the NDP should not be isolated, but taken as an ingetral part of health policy and Health Education Policy and therefore considered in unison and not in contradiction with the New National Health Policy of 1984 as any short-term changes implemented now, cannot be properly integrated with the health policy at a later stage.

THAT as suggested by the Hathi Committee and WHO, there is an urgent need for formulation and adoption of essential drug lists based on the actual health needs of the people.

THAT the essential drugs be made available in generic names.

Contd..2

THAT the production and delivery of essential drugs should be so planned that sufficient essential drugs at affordable prices are available at all times, at all places and to all the people.

THAT the production and sale of all hazardous, irrational and therapeutically useless drug formulations should be immediately stopped.

THAT only unbiased scientific information should be allowed to be given by the pharmaceutical firms to the medical profession and that this information should be approved by the government.

THAT the consumer caution on the product pack should be simple, and in regional languages.

THAT the Health Ministry should independently provide continued information in the sphere of drug usage to the medical profession and to chemists through appropriate measures.

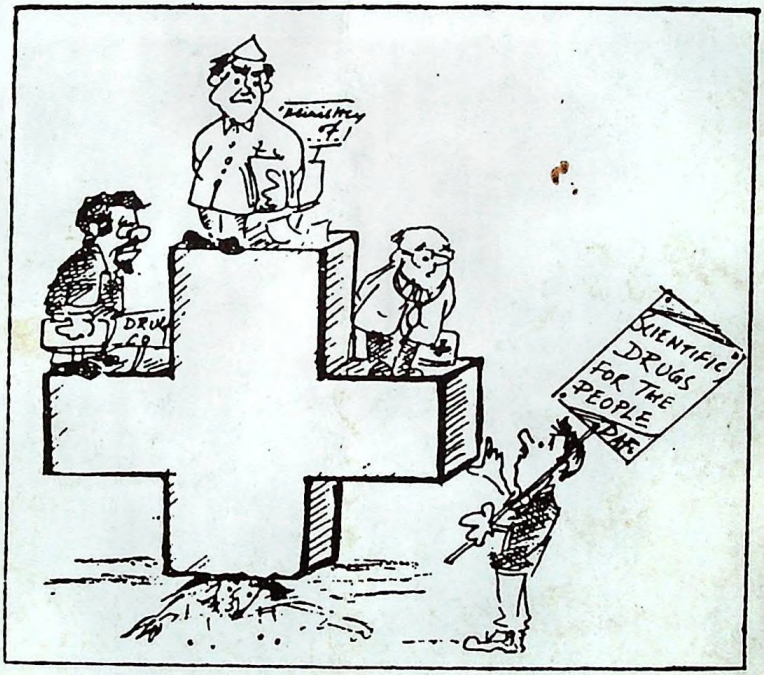
THAT adequate minimum quality control measures should be strictly enforced to give standard quality products.

THAT no change should be made in the existing patent Laws.

THAT the multinationals be made to produce sufficient essential bulk drugs from the basic stage.

Copies of this statement are being sent to the Prime Minister, Ministries of Health, Industry, Drugs and to the concerned officials.

Sd/- for Dr.Mira Shiva
Coordinator
ALL INDIA DRUG ACTION NETWORK



Published, printed and distributed by Dr. S.K. Das on behalf of Drug Action Forum, West Bengal; S/3/5, Srabani, Sector-III, Salt Lake, Calcutta - 700 091 India (Phone: 37-1550). Printed at Autocopiers, 9 Lalbazar Street, Calcutta-1 Phone: 22-0410, 23-2018.