

# **DRUGS & PHARMACEUTICALS**

**VOL. 5, NO. 12**

**DECEMBER 1982**

## **INDUSTRY HIGHLIGHTS**

**National Information Centre for Drugs and Pharmaceuticals  
NISSAT**

**CENTRAL DRUG RESEARCH INSTITUTE, LUCKNOW, INDIA**



# PHARMACEUTICAL INDUSTRY IN INDIA: 'AN OVERVIEW

Dr. P. K. Ghosh

*Manager, Corporate Long Range Planning, Hindustan Antibiotics Limited, Pimpri, Pune*

1. Drugs and Pharmaceuticals Industry in India has made phenomenal progress during the last two decades. During the year of our Independence, the industry existed in the form of a skeleton having an annual turnover of the order of Rs. 100 million only. The turnover comprised of formulations, substantial portion of which were directly imported. A fraction produced in the country was also based on bulk drugs which were imported. Only a few Indian companies used to produce some bulk drugs (active substances) using simple chemical reactions. The multi-national companies started coming to the country mostly after India's Independence and they started marketing formulations imported from their parent companies. Only a few multi-national companies came prior to independence while most of the large companies as of today started operation during the post-independence period. However, due to their superiority in the effectiveness of the medicines they marketed and also due to their aggressive marketing techniques, they could establish themselves in a short period and thereby captured major portion of the market from the Indian companies. A few Indian companies who understood the importance of superior technology, imported the technology from outside and joined the competition with the multi-national companies and also did equally

well. The combined efforts of the Indian private companies as well as the multi-national companies brought about phenomenal progress in the development of the industry. During 1950s the concept of setting up Government owned Public Sector Undertakings was conceived by our Government. As a result of this, the first Central Government owned undertaking namely, Hindustan Antibiotics Limited came into existence sometime in 1952 and the plant was commissioned during 1954. The other unit Indian Drugs & Pharmaceuticals Limited was established in 1962 and the plant was commissioned in 1967. These two units were specifically engaged in the production of bulk drugs (active substances) for supplying to other formulators in the country so as to minimise the dependence on imports of essential bulk drugs required by the country.

2. As on date, there are five Centrally owned Public Sector Undertakings, five jointly owned (State and Central Government) Undertakings, seven State Government Units, twenty-one multi-national companies, about 120 Indian Private Organised Sector Undertakings and about 5000 Units in the Small-Scale Sector. All these units are doing very well in the production of quality bulk drugs and formulations as could be revealed from the following production data.

(Rs. in million)

Year	Bulk drugs	Formulations
1977-78	1640	9000
1978-79	2000	10500
1979-80	2260	11500
1980-81	2400	12000
1981-82	2750	13000

**2.1** Formulation production, as mentioned above, was also supported by imports of bulk drugs which more or less remained stationary in terms of monetary value during the last four years and were about Rs. 800 million in CIF value, al-

though, as mentioned above, the indigenous bulk drug production was on steady increase.

**2.2** Reverting back to production performance, the sectoral break-up of production in the Public Sector, Organised sector and Small-Scale Sector during the last three years is as shown in Table-I.

It will be noticed from Table-I that phenomenal progress had been made by the Indian organised sector of the industry in the production of bulk drugs. The other sectors have also contributed significantly.

**TABLE-I**  
**Sectorial Break-up of Production**

Year	Production of Bulk Drugs (Rs. million) %		Bulk drugs consumed: Indigenous/Imported %		Production of formulation (Rs. million) %	
<b>1978-79</b>						
1. Public Sector	490	24.5			600	5.7
2. Org. Sector						
(a) Indian Cos.	750	37.5			8000	76.2
(b) Multi-national companies	560	28.0				
3. Small-Scale Sector	200	10.0			1900	18.1
	2000	100.0		57		
4. Imported Bulk drugs (estd. landed cost)	1500			43		
	3500			100	1050	100.0
<b>1979-80</b>						
1. Public Sector	590	26			720	6.3
2. Org. Sector						
(a) Indian Cos.	900	40			7780	67.7
(b) Multi-national companies	530	23.4				
(c) Small-Scale Sector	240	10.6			3000	26.0
	2260	100.0		60		



## 4. Imported bulk drugs (landed cost)

1500

40

3760

100

11500

100.0

## 1980-81

## 1. Public Sector

630

26.3

800

6.7

## 2. Org. Sector

## (a) Indian Cos.

980

40.8

## (b) Multi-national companies

530

22.1

} 7900

65.0

## 3. Small-Scale Sector

260

10.8

61.5

3300

27.5

2400

100.0

## 4. Imported bulk drugs (landed cost)

1500

38.5

3900

100.0

12000

100.0

**2.3** In terms of physical quantities of production of important bulk drugs, the Table at Annexure-I may be referred to. It would be seen therefrom that substantial production is being made in the fields of antibiotics, sulfonamides, vitamins, analgesics and anti-pyretics, corticosteroids, anti-TB drugs, Anti-malarials, Anti-dysentery and Intestinal Anti-infectives, Anthelmintics, Anti-Leprotics and Immu-

nological agents. As could be seen from the earlier table, the production of these and other bulk drugs represents more than 60% of the active substance utilised for the production of formulations in India.

**2.4** The production of formulations, various broad category-wise during 1981-82 could be placed as under:

S. No.	Formulations	Rs. in million	% of Total
1.	Antibiotic formulations	2600	20.0
2.	Sulphonamides and other anti-bacterial drugs including Trimethoprim	1545	11.9
3.	Vitamins, Tonics, etc.	1950	15.0
4.	Analgesics/Anti-pyretics/Anti-rheumatics, etc.	1665	12.8
5.	Anti-TB drugs (excluding Streptomycin & Rifampicin)	660	5.1
6.	Anti-dysentery formulations	665	5.1
7.	Anti-malarial drugs	300	2.3
8.	Anthelmintic drugs	100	0.8
9.	Steroids and Hormonal preparations	670	5.2
10.	Anti-diabetic drugs	185	1.4
11.	Other drug formulations	2660	20.4
		13000	100

The formulations produced in India include the entire range demanded and desired by the Medical Profession like Tablets (uncoated, film or press coated), Capsules (soft as well as hard gelatine), Granules, Powders, Ointments and creams, Oral liquids, Injectables (liquids as well as sterile dry powder), Aerosols, Surgical sutures, Sterile and antiseptic bandages etc.

2.5 The customers of medicines are individuals (Doctors, Chemists & Drug-gists and patients) and also the Government (State and Central Government Institutions). The trade sales to individuals is of the order of Rs. 10,000 million while Government Institutional purchase is about Rs. 3,000 million annually. The leading companies in India contributing substantially to the production of formulations are indicated in Annexure-II.

3. There is an elaborate quality control net-work running under the Central Ministry of Health & Family Planning. Under this arrangement, State Drug Control Authorities have been set up in all the large States of the country. It is the responsibility of this Authority to ensure production of quality drugs from every formulating unit in the country. This Organisation in each State authorises manufacture of drugs including drug formulations to various firms under the Drugs Act of India, after inspecting the manufacturing premises and after having been satisfied that manufacture is being organised utilising good manufacturing practice. Inspectors are also constantly keeping a watch on the manufacture by giving surprise visits to the manufacturing premises and collecting samples, and analysing them in their own laboratories to be

satisfied that the quality is being maintained.

3.1 Every large company has, in itself also elaborate quality control department where depending upon formulations marketed, facilities for Chemical, Microbiological and Pharmacological testing are available. As a mandatory practice, every formulator has to test its raw materials and finished products by quality control department and the finished goods are released only after being certified by this department. In many companies, quality assurance cells are created which inter-act with various relevant departments like manufacturing, purchase, medical services, marketing, quality testing and product development departments so as to evolve methods of good manufacturing practice so that quality is built-in in every formulation manufactured and marketed.

3.2 Great care is taken while introducing new products or formulations in the Indian market both by the Government as well as the manufacturers. New products are cleared for marketing by the Government only after being satisfied with results obtained by conducting field trials in selected authorised Hospitals in India. The manufacturers in turn introduce new products only after careful critical in-house evaluation of all the aspects and after a detailed stability study. For labile products, much shorter life is given to the formulations than the bulk drug so that within the life period, the therapeutic claims are ensured.

4. In order to ensure and protect the interests of the consumer as well as the Industry, the Government of India has

adapted a very rational approach in controlling the prices of drugs so that fair selling prices are fixed for every essential formulation manufactured and marketed. The system of price control on medicines and bulk drugs came into being sometimes in 1962. The system has undergone several changes and modifications since then and the price control order now in vogue was promulgated sometimes in 1979. As per this order:

(a) It specifies three categories (Category I, II & III) of bulk drugs and formulations depending upon the essentiality of a drug and the quantum of usage of formulations based thereon. Items which are not covered by these three categories are exempted from price control, since they are not considered essential.

(b) All bulk drugs which are used in the production of price controlled formulations are subjected to price control. The bulk drugs required for Categories I & II formulations are eligible for a "Return" of 14% on net-worth and those going for Category III formulations get a "Return" of 12% on net-worth, when produced indigenously.

(c) The selling prices of bulk drugs required for price controlled formulations are fixed after such enquiry as is deemed fit by the Government. This order also provides "powers" for the fixation of the selling price of imported bulk drugs. Government has also powers to fix the "retention prices", under special circumstan-

ces for individual manufacturers and importers, and also pooled prices for the sale of such bulk drugs to the formulators with a view to providing necessary protection to the indigenous manufacturers.

(d) As for the formulations, the order provides for a ceiling mark-up of 40% on a Category I formulations, 55% on Category II formulations and 100% on Category III formulations. These different slabs of mark-ups on the different categories of formulations and exemption from price control for other drug formulations were intended to ensure that the prices of the life-saving essential medicines are maintained at as low as possible a level for the benefit of the suffering community and at the same time to ensure that the industry could also generate funds for its growth.

(e) As has been indicated above, the price control on formulations are applied on a selective basis. While the prices of formulations categorised under Categories I, II & III can carry only the specific quantum of mark-ups and ceilings, exempted category of formulations is also subject to certain general provisions regarding the printing of retail prices thereon and the profits earned on this category is also subject to the profitability ceilings specified in the order. It will be relevant to mention here that the order provides for a maximum pre-tax return on sales turnover ranging from 8% to 13%.



depending upon the nature of the activity undertaken by the units, i. e., whether the unit is engaged in formulation activity alone or is having basic drug manufacturing activity and/or any Research activity.

(f) By a special notification under 1979 Order, Government have continued the exemption from Price Control in favour of manufacturing units whose annual turnover of formulations do not exceed Rs. 5 million but the prices of such products falling under Categories I & II, if any produced by them, would be subject to their conforming to leader prices (in Categories I & II formulations) as have been notified by the Government. Under the new Order, the manufacturers whose prices were above the leader prices are required to bring them down to the leader's level, whereas the manufacturers whose prices were below the leader-price-level are allowed to increase their prices up to the leader prices level.

(g) The prices of the bulk drugs falling under Categories I & II are being fixed on the basis of a detailed cost-cum-technical study by a suitable agency of the Government. Whenever there is a request for any price escalation or for fixation of price for a new production out of price controlled items, this agency goes into the subject for a cost study and recommends to the Government a fair selling price for fixation. Similarly, any request for increase in the prices of formu-

lations is also scrutinised by this agency before recommending a suitable price to the Government for its approval.

4.1 The price of every formulation marketed in India is stamped on the label. A consumer is, therefore, sure that the price he is paying is a fair price and there is no over-charging.

4.2 A comparison of the prices of various finished formulations available in India and abroad in European countries, U.S.A. and Canada has revealed that cheap prices of formulations in India are either at par or comparable to similar products available internationally. This is the result of Government's determined endeavour to keep the prices of essential life saving drugs within the reach of the common people of India.

5. Reverting back to the fast development of this industry in India, it may be mentioned that the fast development had created a demand for the setting up of supporting industries such as the Chemical and Pharmaceutical machinery manufacturing industry including the processing and packing machinery industry, the industry for process control instruments and also the industry producing laboratory instruments. As on date the bulk drug manufacturing machinery produced in the country includes the whole range of reaction vessels of various materials of construction like stainless steel, glass-lined, rubber-lined, lead-lined, plastic coated mild steel, glass etc., low and medium pressure vessels, storage tanks of various materials of construction, transfer equipment such as pumps of various types, blowers, conveyors etc., vacuum arrangements such as steam ejectors, high

vacuum pumps, mass separation equipment like centrifuges, filter press, dust collectors, liquid-liquid extractors, distillation columns and crystallisers, thermal equipment such as tray dryers, rotary vacuum dryers, fluidised bed dryers etc., pipes, valves and fittings of various types and different materials of construction. Servicing equipment such as step-down transformers, rectifiers, steam boilers, refrigerators, compressors, cooling towers, D. M. water plants etc., are also abundantly available indigenously. The equipment needed for the pharmaceutical processing and packing machinery which are manufactured abundantly in India include the whole range of equipment needed for the manufacture of granules, powders and tablets, including ribbon blenders, mass mixtures, granulators including oscillating type as well as multi-mill, tray and fluid bed dryers, high speed rotary tablet presses with dies and punches upto 45 stations, coating pans, polishing drums, semi-automatic capsule filling and sealing machines, semi-automatic ampouls filling and sealing machines, sterile and non-sterile powder filling machines, laminar flow hoods, semi-automatic bottle washing, filling, sealing and labelling machines for liquid preparations, strip packing machines for tablet and capsule, ampoule-washing machines, packing and checking belts etc. In the area of process control instruments indicating instruments for pressure, temperature, conductivity, pH, flow of fluids, humidity etc., are being

fabricated indigenously. Laboratory instruments such as precision balance, photo-electric calorimeter, visible absorption and emission spectrophotometer, gas liquid chromatograph, different types of calculating machines, thin layer chromatographic instruments are also being manufactured indigenously.

6. It could be seen from the above that:

- (i) Indian Drugs and Pharmaceutical Industry has developed very well. The formulation industry gets more than 60% of the active ingredients from within the country.
- (ii) the quality of bulk drugs as well as finished formulations is maintained at a very high standard by regulations as well as by adapting GMP by the manufacturers.
- (iii) the prices of finished formulations are effectively controlled and regulated by the Government and therefore these are available at fair prices.
- (iv) a very wide range of formulations demanded and desired by the medical profession is available in India.
- (v) the fast development of Pharmaceutical Industry in India had been instrumental to the sound development of Pharmaceutical Machinery Industry in India.



## Production of Bulk Drugs in India

Sl. No.	Item	Unit	Production during	
			1980-81	1981-82
<b>A. Antibiotics</b>				
1.	Penicillins	MMU	336.8	360.6
2.	Streptomycin	MT	227.3	255.5
3.	Chloramphenicol and their esters	MT	161.0	179.0
4.	Tetracycline	MT	167.0	189.0
5.	Oxytetracycline	MT	130.0	114.0
6.	Ampicillin and Semi-Synthetic Penicillins	MT	40.3	62.0
7.	Erythromycin & esters	MT	33.2	29.4
8.	Doxycycline	MT	2.2	1.2
<b>B. Sulphonamides</b>				
9.	Sulphadimidine	MT	444.0	375.0
10.	Sulphacetamide	MT	35.0	61.0
11.	Sulphaphenazole	MT	24.0	45.0
12.	Sulphasomidine	MT	70.5	93.2
13.	Sulphamethoxazole	MT	107.0	167.0
14.	Sulphamethizole	MT	5.6	2.0
15.	Sulphamoxole	MT	125.0	139.0
16.	Sulphaguanidine	MT	316.0	291.0
17.	Sulphadiazine	MT	38.5	60.0
<b>C. Vitamins</b>				
18.	Vitamin A	MMU	60.0	53.0
19.	Vitamin B <sub>1</sub>	MT	19.3	54.5
20.	Vitamin B <sub>2</sub>	MT	9.0	14.2
21.	Vitamin B <sub>12</sub>	KGm	188.3	159.4
22.	Vitamin C	MT	595.0	817.0
23.	Folic Acid	MT	6.0	3.0
24.	Vitamin E	MT	10.4	14.4
25.	Vitamin K	MT	1.1	1.4
26.	Nicotinic acid/amide	MT	66.5	64.8
<b>D. Analgesics, Anti-pyretics etc.</b>				
27.	Analgin	MT	640.0	730.0
28.	Aspirin	MT	886.0	924.0
29.	Phenyl Butazone	MT	66.0	77.0
30.	Oxyphenyl Butazone	MT	57.0	62.0
31.	Paracetamol	MT	394.0	452.0
32.	Ibuprofen	MT	20.0	19.0

**E. Corticosteroids**

33. Prednisolone	Kgs	1423.0	1273.0
34. Dexamethazone	Kgs	127.0	97.0
35. Betamethazone	Kgs	425.0	460.0

**F. Anti-TB drugs**

36. PAS & its salts	MT	405.0	262.0
37. INH	MT	159.0	140.0
38. Thiacetazone	MT	23.0	29.0
39. Ethambutol	MT	30.0	67.0

**G. Anti-malarials**

40. Chloroquin	MT	35.0	59.0
41. Amodiaquin	MT	23.0	26.0

**Anti-Dysentery Drugs**

42. Metronidazole	MT	119.0	128.0
43. Halogenated hydroxyquinolines	MT	232.0	255.0

**Anti-Diabetic Drugs**

44. Insulin	MU	1332.0	2083.0
45. Chlorpropamide	MT	36.0	32.0
46. Tolbutamide	MT	24.0	40.0
47. Glybenclamide	MT	0.73	0.70

**H. Diuretics**

48. Frusemide	Kgs	4110.0	5400.00
---------------	-----	--------	---------

**I. Anaesthetics**

49. Lignocaine	MT	4.6	4.8
50. Procaine	MT	44.0	63.0

**J. Anti-Histaminics**

51. Pheneramine Maleate	MT	8.4	12.6
52. Diphenhydramine HCl	MT	7.2	9.2

**K. Anti-Helmentics**

53. Mebendazole	MT	1.4	2.7
54. Piperazine Hexahydrate	MT	25.0	8.0

**L. Anti-filarials**

55. Diethyl Carbamazine Citrate	MT	26.00	26.0
---------------------------------	----	-------	------

**M. Anti-Leprosy Drugs**

56. Dapsone	MT	21.0	26.0
57. Clofazimine	Kgs	200.0	440.0

**N. Immunological Agents**

58. Triple Vaccine	KL	13.8	17.0
59. Tetanus Anti-Toxin	MMU <sup>a</sup>	12.9	12.0
60. Diphtheria Anti-Toxin	MMU	0.61	0.90

**O. Other Important Drugs**

61. Trimethoprim	MT	25.0	45.0
62. Phenobarbitone	MT	16.1	22.8
63. Ephedrine	MT	22.5	11.7
64. Xanthinol Nicotinate	MT	10.1	15.4
65. Caffeine	MT	87.0	70.5

---



## Leading Companies in the Production of Drugs & Pharmaceuticals in India

### A. Public Sector Undertakings

1. Hindustan Antibiotics Limited
2. Indian Drugs & Pharmaceuticals Limited
3. Bengal Chemical & Pharmaceutical Works
3. Bengal Immunity Company
5. Smith Stanistreet Limited
6. Haffkine Bio-pharmaceutical Corporation
7. Government Quinine Factories
8. Government Opium Factories
9. Maharashtra Antibiotics & Pharmaceuticals Ltd.
10. Kerala State Drugs & Pharmaceuticals Ltd.

### B. Indian Private Sector Undertakings

13. Sarabhai Chemicals
14. Alembic Pharmaceutical Works
15. Cadila Laboratories Limited
16. S. G. Chemicals
17. Unichem Laboratories Limited
18. Ranbaxy Laboratories
19. Raptakos Brett & Co.
20. Deys Medical Stores
21. East India Pharmaceutical Works
22. CIPLA
23. Abbott Laboratories
24. Franco Indian
25. Russel Pharmaceuticals
26. Lyka Laboratories
27. Dolphin Laboratories
28. Boehringer-Knoll Limited
29. Fairdeal
30. Standard Pharmaceuticals
31. Rallis India Limited
32. Nicholas Laboratories
33. Themis Pharmaceuticals
34. P. C. I. India Ltd.
35. Wockhardt Ltd.
36. Unique Pharmaceuticals
37. Biological Evans
38. Geoffrey Manners
39. U. S. Vitamins
40. Searle India Limited
41. Duphar Interfran
42. Aristo Pharmaceuticals
43. Walter-Bushnell
44. Martin Harris

45. Lupin Laboratories
46. Pharmed Pvt. Ltd.
47. Astra-IDL Limited
48. IPCA Lab.
49. Reckitt & Colman
50. Albert David
51. Gufic Laboratories
52. Biochem
53. Neopharma
54. Mac Laboratories
55. Uni-UCB
56. Chemo Pharma Laboratories
57. Gujarat Pharmaceuticals
58. G. D. Pharmaceuticals
59. Mount Mettur Pharmaceuticals
60. Jagson Pal
61. Juggat Pharma
62. Smith & Nephew
63. Leucoplast India
64. Chowgule
65. Torrent Laboratories
66. Citadel Pharmaceuticals
67. Medley Laboratories

### C. Multi-national Companies

68. Glaxo Laboratories
69. Pfizer (India) Limited
70. Hoechst Pharmaceuticals
71. Burroughs Wellcome
72. Boots India Limited
73. Sandoz India Limited
74. Parke-Davis India Limited
75. E. Merck India Limited
76. May & Baker
77. John Wyeth
78. Warner Hindustan Limited
79. Roche Products
80. Merck Sharp & Dohme
81. Lederle (Cyanamide India) Limited
82. Organon India Limited
83. Ciba-Geigy Limited
84. Bayer India Limited
85. A. C. C. I.
86. Johnson & Johnson
87. Richardson Hindustan
88. Smith Kline & French India Ltd.