



Indian Pharmaceutical Industry - A Genesis

Dr. Syed Ali Reza

M.A. (Economics), Ph.D. (Economics), MBA (Finance & Marketing)
Branch Manager-ICICI Bank -Budhana, Muzaffar Nagar, UP, India

Email: syedalireza1@gmail.com

Abstract

The Indian Pharmaceutical Industry manufactures about 400 bulk drugs belonging to various therapeutic segments. The pharmaceutical industry produces bulk drugs belonging to major therapy groups. India ranks 4th worldwide accounting for 8% of the world's production (in terms of volume) and 13th in terms of value.

It is estimated that by the year 2018, the Indian pharmaceutical industry has the potential to achieve over Rs 1, 00,000 crore in formulations and bulk drug production. The industry now produces bulk drugs belonging to all major therapeutic groups requiring complicated manufacturing process and has also developed Good Manufacturing Practices (GMP) facilities for the production of different dosage forms.

At a growth rate of 9% per year, the pharmaceutical industry in India is well set for rapid expansion. The health care market has opened a window of opportunities in the medical device field and has boosted clinical trials in India. India's impact on the global biotechnology and pharmaceutical industry is accelerating. From quality supply of active pharmaceutical ingredients (APIs) to discovery of new chemical entities (NCEs), this sector is finally coming of age.

Keywords: Drug, Pharmaceutical, Patent, IPR, Formulation.

1. Introduction

For the Medicine and Surgery in India, the studies can be divided into two parts –

- 1.1) Pre-Independence and;
- 1.2) Post- Independence

1.1) Pre-Independence

Indian medicine has a long history. Its earliest concepts find a place in the sacred writings of the Vedas, which possibly date as far back as the 2nd century B.C. historically, the system of medicine called Ayurveda was received by Dhanvantari from the creator-Brahma and Dhanvantari was considered as the God of Medicine. The period of Vedic medicine lasted till 800 B.C. The golden age of Indian Medicine from 800 B.C. until about A.D. 1000, was marked by the production of the



medical treatises known as the Caraka-Samhita and Susruta-Samhita attributed respectively to Caraka, a physician and Susruta, a surgeon.

The important ways of active treatment were referred to as five procedures: the administration of emetics, water enemas, purgatives, oil enemas and sneezing powders.

Caraka knew 500 medicinal plants, and Susruta knew 760. But animal remedies (such as the milk of various animals, bones, gallstones) and minerals (sulfur, arsenic, lead, and copper sulfate, gold) were also employed. The physicians collected and prepared their own vegetable drugs. Among those that eventually appeared in western pharmacopoeias were cardamom and cinnamon. As the result of the hard religious beliefs of Hindus, hygienic measures were much useful in treatment.

In surgery, ancient Hindu medicine reached its zenith. Operations performed by Hindu surgeons included splinting of fractures, amputations, cesarean sections, and stitching of wounds etc. In two types of operations especially, the Hindus were outstanding, stone in the bladder (vesical calculus) and plastic surgery. Hindu surgeons also operated on cataracts by couching or displacing the lens to improve vision.

Under the Mughal Emperors, Arab medicine came to India. It took root in India, under the name of Unani, mainly because there was so much in common between the old Indian system and the new Unani system. The term Unani is derived from the Sanskrit Yavana meaning Greek. The Unani system continues to this day in India.

Western medicine was introduced in the colonies by the Europeans, came to be viewed by the natives as scientifically advanced or modern medicine. The western system of medicine was later named Allopathy by Hanemann to distinguish it from his own system Homeopathy.

The modern pharmaceutical industry under the colonial rule began in India when the Bengal Chemical and Pharmaceutical Works were established in Calcutta. Subsequently and in quick succession, institutes like King's Institute of Preventive Medicine, Chennai, Pasteurs Institute, Coonor, Central Drug Research Institute, Kasauli and other institutes were set up. The Indian system of Medicine and Homeopathy consist of Ayurveda, Siddha, Unani and Homeopathy and therapies such as Yoga and Naturopathy.

Some of these systems are indigenous and others such as Homeopathy have over the years become a part of the Indian tradition. Prior to the advent of modern medicine, these systems had, for centuries, catered to the healthcare needs of the people; these systems are widely used even today because their practitioners are acceptable both geographically and culturally are accessible and their services and drugs are affordable.



1.2) Post-Independence

Post- independence, India made important investments in creating over 1000 research institutes, knowledge factories churning out scientists. The setting up of penicillin factory at Pimpri, in the early 50's and the establishment of Indian Drugs and Pharmaceuticals Limited (IDPL) plants at Rishikesh and Hyderabad in the 60s have been milestones in the history of pharmaceutical industry in the country. These have been the building blocks on which the structure of the pharmaceutical industry in India has been built.

The public sector investment has been the engine of growth for the industry as a whole in the last three decades. However, of late, the five public sector units, namely, Indian Drugs and Pharmaceuticals Limited (IDPL), Hindustan Antibiotics Limited (HAL), Bengal Chemicals and Pharmaceuticals Limited (BCPL), Smith Stan Street Pharmaceuticals Limited (SSPL) and Bengal Immunity Limited (BIL), have all been in the red due to outdated technology, excessive workforce, high overheads, weak marketing set-ups, excessive reliance on institutional sales, etc. All these units were referred to BIFR and the revival package has failed.

The Indian Pharmaceutical Industry is in the transitional phase today. With the introduction of product patent regime, the dynamics of the industry is rapidly changing. To meet the challenges in the post 2005 era, the pharmaceutical industry in India is preparing itself through restructuring and consolidation, giving emphasis to basic research, strengthening product portfolios and leveraging process skills to enter the highly regulated markets.

2. Nature and Scope of Study

The demographic statistics in India reveal the country has a population of more than one billion (100 crore), 48% female and 52% male, and the population growth rate is 1.6% and 58% of population is aged less than 25 years, and 83% below 45 years. Over 70% of our population lives in rural areas and 302 towns account for 65% of the urban population. The per capita income is estimated at US\$ 400 (Rs 18,000) and the population earning income over US\$ 1000 per annum (Rs 45,000), the middle class is approximately 150 million (15 crore).

Statistics on the prevailing healthcare system shows the country has 150,000 pharmacies in urban area and the same number in rural areas. About five lakh doctors and 6 lakh each nurses and pharmacists work in 15,000 hospitals, of which 55% are Government owned and 45% by others. It also has 180,000 (130,000 are sub-centers with basic services) dispensaries and health centers. Total bed strength in hospitals is about 1,000,000 of which 60% is in the public sector. The concept of medical insurance is very limited and reimbursement is allowed mainly from companies/institutions to employees.

The pharmaceutical industry in India is currently valued at Rs72,000 crore approx). There are about 23,000 manufacturing units, making about 6,500 brands in 77 therapeutic segments .

3. Value of production of bulk drugs and formulations

The key to success of Indian pharmaceutical companies is their ability to retain their cost advantage while matching the quality standards of the west. But lower costs alone cannot be enough. Availability of skilled man-power and a favorable regulatory environment that assures compliance with global norms are the other two legs underpinning success.

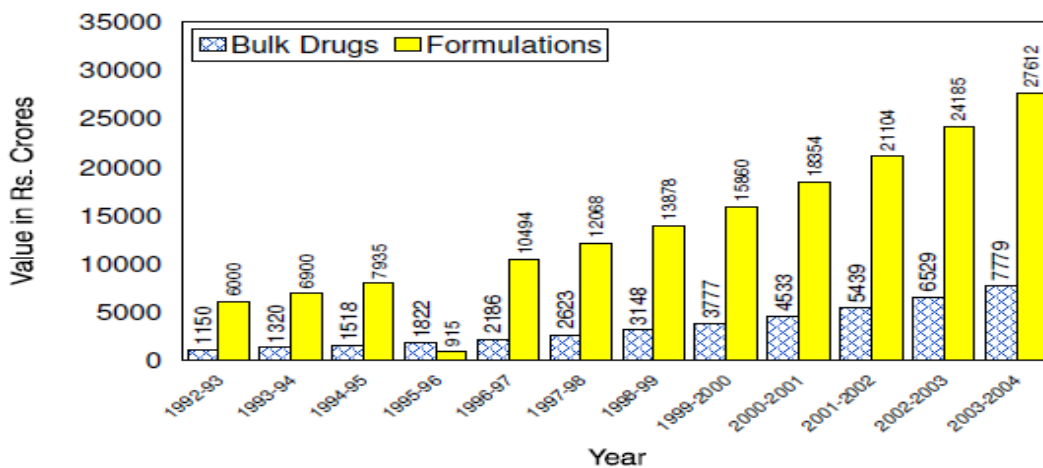
Table-1 Value of Production of Bulk Drugs and Formulations During the years 92-93 to 2003-04

(Rupees in Crores)

Year	Bulk Drugs	Growth (%)	Formulations	Growth (%)
1992-93	1150	-	6000	-
1993-94	1320	14.8	6900	15.0
1994-95	1518	15.0	7935	15.0
1995-96	1822	20.0	9125	15.0
1996-97	2186	19.9	10494	15.0
1997-98	2623	20.0	12068	15.0
1998-99	3148	20.0	13878	15.0
1999-2000	3777	16.7	15860	12.5
2000-2001	4533	20.0	18354	15.5
2001-2002	5439	19.7	21104	15.0
2002-2003	6529	19.3	24185	14.6
2003-2004	7779	19.14	27692	14.5

Source: Report of the Working Group on Drugs and Pharmaceuticals for the period (1992-93 to 2003-04): IDMA data bank.

Value of Production of Bulk Drugs and Formulations from 1992-93 to 2003-04; Graph-A





4. Bulk drugs and Formulations

The domestic pharmaceutical industry has shown a consistent growth rate both in terms of value and volume for bulk drugs and formulations starting with the base year 1992-93. In 1992-93, the value of production of Bulk drugs and formulations was Rs 1150 crore and Rs 6000 crore respectively. Overall the growth pattern has been consistent over the years in the value of production of Bulk drugs and formulations. In 2003-04, the value of production of bulk drugs and formulations was Rs 7779 crore and Rs 27692 crore respectively with a growth of 19.14% in bulk drugs and 14.5% in formulations. For bulk drugs the growth percentage over the years has been in the range of 14.8% to 20%. Similarly for formulations the percentage growth over the years has been in the range of 12.5% to 15.0% respectively.

Bulk drug production recorded a CAGR of 20% during the period 1992-93 to 2003-04 which is higher than the growth in the overall production of pharmaceuticals having CAGR of 17.5%, during the same period. The proportionate share of bulk drugs has increased from 16.08% in 1992-93 to 22.0% in 2003-04.

5. Foreign Direct Investment (FDI) in Drugs and Pharmaceuticals

- a) FDI up to 74% in the case of bulk drugs, their intermediate pharmaceutical and formulations (except those produced by the use of recombinant DNA technology would be covered under automatic route).
- b) For manufacture of bulk drugs from basic stages and their intermediates and bulk drugs produced by the use of recombinant DNA technology as well as the specific cell/tissue targeted formulations provided it involves manufacturing from basic stage.

6. Provisions of Union Budget for the Pharma Sector

- (i) Weighted deduction on in-house R&D expenditure extended for a period of five or more years.
- (ii) Service Tax Exemption to DCGI2 approved CRO3s offering clinical trials for technical testing and analysis services for testing of new drugs.
- (iii) Peak customs duty reduced to 10%.
- (iv) Concessional rate of 5% customs duty plus Nil CVD on specified items extended to all research institutions registered with DSIR4.
- (v) Additional 15 imported items for R&D purposes allowed to be imported at 5% customs duty.
- (vi) Increased budgetary allocation towards AIDS control and immunization for polio.

7. Conclusion



With several companies slated to make investments in India, the future scenario of the Indian pharmaceutical industry looks pretty promising. The country's pharmaceutical industry has a great potential for growth considering the projects that are in pipeline.

The basic objectives of Government's policy relating to the drugs and pharmaceutical sector were enumerated in the Drug Policy of 1986. These basic objectives are still remaining largely valid. However, the drug and pharmaceutical industry in the country today faces new challenges on account of liberalization of the Indian economy, the globalization of the world economy and on account of new obligations undertaken by India under the WTO agreements. The need for radically improving the policy framework for knowledge-based industry has also been acknowledged by the Government. The Prime Minister's Advisory Council on Trade and Industry has made important recommendations regarding knowledge-based industry.

To ensure abundant availability at reasonable prices within the country of good quality essential pharmaceuticals of mass consumption and at the same time strengthening the indigenous capability for cost effective quality production and exports of the pharmaceuticals by reducing various barriers to the trade in pharmaceutical sector. To strengthen the system of quality control over drug and pharmaceutical production and distribution to make quality an essential attribute of the Indian pharmaceutical industry and promoting rational use of pharmaceuticals and also to encourage R&D in the pharmaceutical sector in a manner compatible with the country's needs and with particular focus on diseases endemic or relevant to India by creating an environment conducive to channelizing a higher level of investment into R&D in pharmaceuticals in India and lastly creating an incentive framework for the pharmaceutical industry which promotes new technologies and new drugs.

The Pharmaceutical Policy 2002 has made provisions for the following:

1. Exemption from price control for a new drug developed through indigenous R&D for a period of 15 years from the date of the commencement of its commercial production in the country.
2. Exemption from price control for –
 - (i) a drug manufactured using indigenously developed process; and
 - (ii) a formulation with a new delivery system developed indigenously and patented under IPA.

The exemption would be valid from the date of commencement of commercial production of the drug till the expiry of the patent under IPA.

3. The pharmaceutical policy provides for reduction in span of price control. For bringing a bulk drug under price control, two criteria would be considered –



- (i) mass consumption nature of drug and
- (ii) absence of sufficient competition in such drugs.

References

1. Anand, C. K., (2005); New Vistas in Indian Pharma Market Post-2005, Chronicle Pharmabiz (Sp. Suppl. Arab Health), Dubai, 2005, pp. 15.
2. Jain, S. M., (2003); APIs and Formulations – The two arms, Chronicle Pharmabiz , Mumbai, pp. 15.
3. Gandhi, G. K., (1992); Indian Medicine, Encyclopedia Britannica, Vol. 23, S. Chand & Co., New Delhi, pp. 886.
4. Babu, L., (2002); Science Panorama, Manorama Yearbook, p. 230.
5. Kumar, A. R., (2004); Impact of TRIPS on Indian Pharma, Chronicle Pharmabiz, Mumbai, pp. 78.
6. Pal, S., (2003); Healthcare during the Tenth Plan, Employment News, N. Delhi, 25-31, pp. 7.
7. Sivayya, K. V. and Das, V. B., (2001); Indian Industrial Economy, S. Chand & Co. Ltd., N. Delhi, pp. 430.
8. Sundaram, K., (2003); Production of Chemical entity in India, Dept. of Chemicals and Petrochemicals–Ministry of Chemicals and Fertilizers. Retrieved from <http://chemicals.nic.in./pharma4.htm>.