

Pharmaceutical Policy

***Department of Industries & Commerce
Government of Haryana***

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1. Preamble: Industry overview in India

The Pharmaceutical industry is one of the fastest growing industrial sectors and India is among the leading countries for producing generic drugs and is known as the 'Pharmacy of the World'. Generic drugs/Formulations produced in India are not only consumed domestically, but also in developed and developing countries across the globe. Currently topping the science-based industries in India, the Pharmaceutical sector is an industry with over 20,000 registered units. This sector is one of the nation's prestigious sectors with a global reputation for its cost-effective quality. Ranked highly specially among the developing countries, the industry in India it ranges from generic drugs formulations to APIs (Active Pharmaceutical Ingredients), bulk drugs and medical devices.

Majorly competitive in nature, the sector is also regulated by the Government in terms of price controls through NPPA (National Pharmaceutical Pricing Authority). 70% of the nation's demand and 30% of the need of the international market is met by the domestic Pharmaceutical industry. About 250 large enterprises and 8000 MSMEs dominate this sector in India.

India is among the top 5 emerging pharma markets in the world. With increase in health awareness and life expectancy, the domestic consumption of medicines is also increasing.

Salient features of Pharma industry in India:

- Third largest pharmaceuticals market by 2020 in terms of incremental growth
- 20% of global exports in generics, making it the largest provider of generic medicines globally
- Industry revenues are expected to grow by a CAGR of 12% during 2012-20 and reach USD 45 bn.

Over the years, India has emerged as a key manufacturing hub for generic formulations by producing cost-effective and quality drugs. As a result, the demand for input chemicals has increased. Domestic demand is expected to remain strong as number of patients having access to healthcare services increases. With pharmaceutical companies taking steps to meet US Food and Drug Administration (USFDA) norms, export growth is expected to pick up. Presently, it is the need of the hour for India to focus on increasing bulk drugs and API production within the country itself, to end the dependency on other countries.

2. Policy targets

2.1 Vision

To transform Haryana in to a hub for the Pharmaceutical industry to do business and thrive; by facilitating a conducive and holistic industrial ecosystem comprising robust infrastructure, financial assistance and a simplified regulatory regime.

2.2 Mission

- (i) Implement an enabling regulatory environment for Pharmaceutical sector, with investor friendly and time-bound clearance delivery system
- (ii) Focus on holistic Pharmaceutical cluster development
- (iii) Provide fiscal and non-fiscal benefits to units setting up in the Pharma Park, in a dedicated and streamlined manner
- (iv) Develop quality industrial infrastructure to support entrepreneurs in the State
- (v) To enhance human capital and effectively bridge the gap between academia and industry to optimally utilize resources
- (vi) Provide land at subsidized rates to entrepreneurs for establishing Pharma units
- (vii) Encourage environment friendly activities in the Pharma industry
- (viii) Effectively utilize the Single Window clearance mechanism, providing clearances in a time-bound manner
- (ix) Ensure time-bound implementation and effective monitoring of the Pharmaceutical policy

2.3 Objectives

- (i) To attract investment in the Pharmaceutical sector to the tune of INR 2000 Cr.
- (ii) To generate 25,000 new jobs in the Pharmaceutical sector
- (iii) Successfully establish a state-of-the-art Pharma Park at Karnal
- (iv) To develop Haryana into a hub for pharmaceutical manufacturing by facilitating and creating a holistic industry, academia and R&D ecosystem

3. General terms and conditions

- For the purpose of this policy all terms and definitions shall be as per the Haryana Enterprises Promotion Policy 2015
- This policy will be valid for 5 years from the date of notification or till the time any new policy/amendment is introduced by Government of Haryana, whichever is earlier
- Doubts relating to interpretation of any term or any provision under this policy will be referred to the Department of Industries & Commerce, Government of Haryana, for clarification/resolution. The decision of the State government shall be final and binding for all stakeholders in all cases.

4. Industry overview: Haryana perspective

The Government of Haryana, under the leadership of the visionary Chief Minister, is proactively involved in promoting the Pharmaceutical sector in Haryana.

4.1 Strategic location

Haryana's enjoys a locational advantage, characterized by its geographical confluence with economic corridors (DMIC, AKIC, and Eastern peripheral corridor), Special Economic Zones, investment regions and big ticket infrastructure projects. With a strategic location in close proximity to the National Capital Region, excellent air, road and rail connectivity and two international airports, Haryana is an ideal destination for new businesses to flourish. Through its Enterprise Promotion Policy 2015, the Government of Haryana lists the Pharmaceutical sector as one of the focus sectors for development. The State at present, is one of the leading exporters in the nation with the total value of State exports valued at INR 69,485 crores (3 year average-2014-2017). Therefore in line with its global orientation towards facilitating exports in the Pharma sector, the State Government endeavors to provide the necessary support by way of creating the necessary land bank, technology ecosystem and transport facilities.

4.2 Quality infrastructure

The Government of Haryana has taken key initiatives in developing enabling industrial infrastructure to support new entrepreneurs.

- Haryana ranks 4th in the infrastructure Index developed by the Central for Monitoring Indian Economy (CMIE) 2012
- Approximately 2/3rd of Haryana lies in NCR region- 13 districts of the state are part of National Capital Region (NCR)- one of largest consumption & trade zone of India
- The entire State is within a 250 km radius from the international airports at New Delhi & Chandigarh
- Industrial corridors - beltway to spur economic activity
 - 15 National Highways pass through Haryana
 - Delhi - Mumbai Industrial Corridor (DMIC)
 - Kundli-Manesar-Palwal Expressway (KMP)

4.3 Upcoming Pharmaceutical Park at Karnal

- The State intends to establish a Pharma Park at Karnal. Karnal is a centrally located district with excellent road (situated on NH-) /rail (Delhi Ambala broad gage line, where Delhi and Ambala are both junctions) and air connectivity
- The Pharma Park will comprise two separate zones for
 - i. Formulation manufacturing
 - ii. API manufacturing
- The State government will provide common facilities such as Common Cluster Lab and Common Effluent Treatment Plant for this Park (in the formulations manufacturing zone) with guidelines and designs provided by the Haryana State Pollution Control Board
- Since the State government intends to establish CETP for formulation units in the Karnal Pharma Park, the pollution clearance will be obtained by the SPV/implementing agency
- For API and bulk drug units, being polluting industries in the red category, ETP plants will be set up by the individual units themselves. However, the technical guidance and clearances will be provided by the State Government.
- New units setting up in the Pharma Park at Karnal will be eligible for a special package of incentives, in addition to benefits as per Haryana Enterprises Promotion Policy 2015 (as specified in section 5.2)

5. Fiscal incentives

5.1 Incentives applicable for new units:

Fiscal incentives for new units will be applicable as per investment category, as mentioned in the Haryana Enterprises Promotion Policy 2015.

5.2 Incentives applicable for units setting up in the upcoming Pharma clusters and Parks:

The Government of Haryana envisages to establish a centrally located Pharmaceutical Park at Karnal.

In addition to incentives offered under the Haryana Enterprises Promotion Policy 2015, all new units setting up in the Pharma Parks in the State will be eligible for a special package of incentives as follows:

Sr. no	Parameter	Incentive
1	Capital Subsidy	Reimbursement of 25% of cost of plant and machinery subject to a maximum of INR 50 lakh
2	Interest Subsidy	To the extent of 5% per annum for 5 years in the form of reimbursement of interest paid on loan taken to meet the working capital requirements, subject to annual ceiling of INR 25 lakh per annum per unit.
3	Employment generation subsidy *Only if applicable	For capacity building of persons belonging to Haryana (skilled/semi-skilled, the subsidy @ Rs. 36,000 per year for SC/ Women and Rs. 30,000 per year for General category for 5 years

6. Simplified regulatory regime

6.1 Integration of Pharma related clearances in the Single Window

In order to simplify the regulatory processes for new investors in the Pharma industry in Haryana, the Government of Haryana will integrate all Pharma sector related clearances with the Single Window portal of the State i.e HEPC (Invest Haryana- www.investharyana.in), to provide clearances in a time-bound, completely online, and streamlined manner.

6.2 Auto/deemed renewal of licenses

The Government of Haryana for the purpose of Ease of Doing Business has omitted the word “renewal” and made the drug manufacturing licenses/approvals for entrepreneurs to remain valid in perpetuity unless and until suspended or cancelled. The licensee can thus retain their licenses, by payment of retention fee online.

6.3 Timely grant of manufacturing licenses

All Pharma manufacturing licenses in the purview of the State will be integrated in the Invest Haryana (HEPC) portal. Timelines for all licenses will be included in HEPA, 2015 i.e granting of clearances in 30 days and deemed clearances in 45 days.

6.4 Approval for manufacturing and sale of all rational drugs that have been approved by neighbouring state licensing authorities/expert committees

Approvals will be granted by the Government of Haryana to all rational drugs which

- have been approved by neighbouring State licensing authorities and declared rational by the expert committees constituted by Government of India

- Are not banned/prohibited by Government of India under Section 26-A of Drugs Act

7. Infrastructure augmentation and State support

7.1 Support for Developers of Pharma Park at Karnal: 100% of the cost of external and internal infrastructure development will be borne by State Government subject to a ceiling of 50 Cr., to develop Pharma Park in Karnal

7.2 Support for setting up of Common Effluent Treatment Plant (CETP) for Formulations and API units in Pharma Park/Cluster: The Government of Haryana intends to support Pharma units in the State by bearing the capex for setting up of secondary ETP (CETP) for units in Pharma Park/Cluster. The running expenditure for the same will be borne by the units as per their usage.

7.3 Promotion of API/Bulk Drug manufacturing Parks: The Government of Haryana, dovetailing with the focus of the Central Government, will work towards dedicatedly promoting and supporting the setting up of API Parks in Haryana.

7.4 State Drug Testing Laboratory: The Government will provide additional manpower and facilities in terms of State Drug Testing Laboratories. The Government will continuously upgrade the State Drug Testing Laboratories, which will be equipped with state-of-the-art modern testing equipment and infrastructure. The Government intends to establish mobile Drug Testing Laboratories to increase the confidence of consumers and ensure easy accessibility of testing facilities for all citizens.

7.5 Common Cluster Laboratory: The Government of Haryana intends to provide support to the Common Cluster Laboratory established at Karnal which is equipped with modern testing equipment and facilities. This will reduce the cost of testing borne by the units in the Pharma Park and help in assuring the quality of drugs.

7.6 Support for research companies and laboratories: The Government of Haryana will facilitate collaborations and matchmaking between research organizations, Pharma industry players and educational institutes.

7.7 Simplification of tender processes: The Government of Haryana intends to simplify tender processes in the State by introducing a provision of obtaining tender participation certificates online within a timeline of 2 working days. This facility will be

integrated with the Single Window system of the State along with the provision of e-signatures by the concerned authorities.

7.8 Promotion of Government of India- Scheme for development of Pharmaceutical industry

In order to facilitate the growth of the domestic pharmaceutical to play a lead role in the global market and ensure availability of good quality pharmaceuticals of mass consumption thereby assuring drug security in the country, the Department of Pharmaceutical, Ministry of Chemicals and Fertilizers, Government of India, has introduced a scheme for development of the pharmaceutical industry in India which comprises five sub-schemes namely:

- (i) Assistance to Bulk Drug Industry for Common Facility Centre (CFC):
Focused on providing easy access to standard testing and infrastructure facilities and value addition in the domestic Bulk Drug Industry through creation of common world class facilities, strengthening existing infrastructure facilities and reducing the cost of production by 20-25% in the Bulk Drug Park
- (ii) Assistance to Medical Device Industry for Common Facility Centre
Focused on providing easy access to standard testing and infrastructure facilities and value addition in the domestic Medical Device Industry through creation of common world class facilities, strengthening existing infrastructure facilities and reducing the cost of production significantly in the Medical Device Park
- (iii) Cluster Development Programme for Pharma Sector
Focused on providing easy access to standard testing facilities and value addition in the domestic pharma industry especially to SMEs through creation of common world class facilities
- (iv) Pharmaceuticals Technology Upgradation Assistance Scheme
Focused on promotion, development and export promotion in Pharma sector by extending financial support for conduct of seminars, conferences, exhibitions as well as conducting studies/consultancies for facilitating growth
- (v) Pharmaceutical Promotion and Development Scheme
Focused on providing interest subvention to the eligible Small and Medium Scale Pharma Units having GMP compliant manufacturing facilities both for Bulk Drugs and Pharma Formulations, which are intending to upgrade their manufacturing infrastructure to attain

WHO-GMP norms, and have to secure loan from any Financial Institution for upgrading their infrastructure and technology

In this regard, Government of Haryana will align with the guidelines shared by Government of India for the aforementioned scheme comprising five sub-schemes, to boost the Pharmaceutical industry in Haryana.

8. Human capital development

- 8.1 **Training programmes** will be designed for pharma workers under the **Haryana Skill Development Mission**. Under this training model, partnerships between Universities and Pharma companies will be facilitated by the State Government. Specific and industry-aligned job courses will be designed and introduced at Haryana Vishwakarma Skill University, as per industry requirements, thus increasing the competent labour pool in the State.
- 8.2 The Government of Haryana will facilitate **industrial and regulatory trainings for B.Pharm/M.Pharm students in industrial units of the Pharma Park at Karnal**