

Haryana Pharmaceutical and Medical Devices Manufacturing Policy



Department of Industries
& Commerce,
Government of Haryana



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List of Acronyms

API	Active Pharmaceutical Ingredient
CAGR	Compounded Annual Growth Rate
CDMO	Contract Development and Manufacturing Organizations
CGTMSE	Credit Guarantee Fund Trust for Micro and Small Enterprises
CLU	Change of Land Use
CoE	Center of Excellence
CRO	Contract Research Organizations
EDC	External Development Charges
EEC	Empowered Executive Committee
ETP	Effluent Treatment Plant
EU	European Union
FCI	Fixed Capital Investment
FDI	Foreign Direct Investment
GoH	Government of Haryana
Gol	Government of India
GST	Goods & Services Tax
HEEP	Haryana Enterprises and Employment Policy
HEPB	Haryana Enterprises Promotion Board
HEPC	Haryana Enterprise Promotion Centre
IIT	Indian Institute of Technology
IMT	Industrial Model Township
INR	Indian National Rupee
ITC	Input Tax Credit
IVD	In-Vitro Diagnostic
MDR	Medical Device Rules
MSME	Micro, Small and Medium Enterprises
MSMED	Micro, Small and Medium Enterprises Development Act
OEM	Original Equipment Manufacturer
PLI	Production Linked Incentive
R & D	Research and Development
SGST	State Goods & Services Tax
USD	United States Dollar



1. Background

Public health underpins sustainable economic development: a healthy population is both a prerequisite and a driver of productivity, innovation and social well-being. In this context, the pharmaceutical and medical-devices sectors are indispensable engines of growth—advancing cutting-edge solutions, enhancing patient outcomes and strengthening the very foundations of our healthcare infrastructure. Beyond their direct role in safeguarding lives, these industries generate high-quality employment, foster research-and-development ecosystems, and elevate India’s competitiveness on the global stage.

Globally, the pharmaceutical industry is valued at roughly USD 1.6 trillion, with projections to reach USD 2.6 trillion by 2030¹. India commands a 3% share of this market (USD 49.7 billion in 2023) and it is expected that the domestic market size will rise to USD 130 billion by the end of the decade². As the world’s largest supplier of generics—meeting 20% of global generic-medicine demand and 60% of vaccine requirements—our strengths lie in cost-efficient manufacturing, a vast skilled workforce and a well-established regulatory framework. India is the third largest producer by volume of pharmaceutical products. However, it stands at only 11th in terms of value of pharmaceutical products produced³. Dependence on China for 72% of bulk drugs and intermediates, plus increasingly stringent international standards, underscore the need to move up the value chain into specialty generics, biosimilars and innovative therapies⁴.

Meanwhile, the global medical-devices market stands at ~ USD 930 billion⁵. India’s domestic market at USD 15.35 billion in 2023 ranks fourth in Asia⁶ but still relies on imports for approx. 80% of total demand, particularly in high-end diagnostics, imaging systems and advanced implants. Domestic output today is heavily weighted toward lower-technology products (stents, disposables, basic surgical tools), and limited R&D investment constrains innovation. The National Medical Devices Policy 2023 targets a ten-fold expansion (to USD 50 billion) by 2030 and a global market share boost from under 2% to over 10% by 2048—but realizing these ambitions demands stronger domestic manufacturing capabilities, deepened industry-academia collaboration and streamlined regulatory pathways.

The Draft Haryana Pharmaceutical and Medical Devices Manufacturing Policy aims to revamp the State’s pharmaceutical and medical device industry by encouraging local production, promoting research & development, and improving the availability of affordable medicines to

¹ IQVIA: Global Use of Medicines Outlook, 2024

² India Brand Equity Foundation (IBEF)

³ Department of Pharmaceuticals, Govt. of India

⁴ NITI Aayog Report

⁵ Fortune Business Insights - Medical Devices Market Size & Industry Analysis

⁶ India Brand Equity Foundation (IBEF)



the citizens. The policy focuses on creating a conducive environment for the growth of the pharmaceutical and medical devices industry in the State and aims to attract investments in the sector by providing a range of fiscal and non-fiscal incentives for manufacturing units setting up or expanding in the State. The Policy also focusses on promoting exports by facilitating international certifications and global market linkages and aims at creating a robust ecosystem for research and development and skill development in the sector.

By harnessing Haryana’s existing industrial strengths and fostering a robust ecosystem for both pharmaceuticals and medical devices, this policy aims to bolster India’s self-reliance, generate high-value employment, and deliver cutting-edge healthcare solutions to citizens—positioning the State as a model of innovation, growth and public-health excellence.



2. Definitions

- 2.1 Active Pharmaceutical Ingredient (API)/ Bulk Drugs:** Active Pharmaceutical Ingredient (API) or Bulk Drug means any substance or mixture of substances intended to be used in the manufacture of a drug (medicinal product) and which, when used in the production of a drug, becomes an active ingredient of that drug product. Such substances are intended to furnish pharmacological activity or other direct effects in the diagnosis, cure, mitigation, treatment or prevention of disease, or to affect the structure or any function of the human body. For the purposes of this policy, Active Pharmaceutical Ingredient (API) and Bulk Drug shall have the same meaning.
- 2.2 Biologics/ Biological Products:** Biologics or Biological Products refer to medicinal products that are derived from living organisms or contain components of living organisms and are produced using biotechnology or other biological processes. These products may be derived from human, animal or microbial sources and include, but are not limited to, vaccines, blood and blood components, recombinant proteins, monoclonal antibodies, cell and gene therapy products and other similar biological therapeutics used for the diagnosis, prevention or treatment of diseases.
- 2.3 Biosimilars or Similar Biologics:** Biosimilars or Similar Biologics are biological products that are demonstrated to be similar in terms of quality, safety and efficacy to an already approved reference biological product, based on comprehensive comparability studies. Such products are approved by the regulatory authority following evaluation of analytical, non-clinical and clinical data in accordance with applicable regulatory guidelines
- 2.4 Drug Intermediates:** Drug Intermediates means a material produced during intermediate stages in the manufacture or synthesis of an Active Pharmaceutical Ingredient (API), which undergoes further molecular change or processing before it becomes an API.
- 2.5 Generic Drug:** Generic Drug means a drug product that is intended to be interchangeable with a reference or innovator drug and is manufactured without a license from the innovator company. A generic drug has the same dosage form, safety, strength, route of administration, quality and performance characteristics as the reference drug.
- 2.6 Key Starting Material (KSM):** A raw material, intermediate or an API that is used in the production of an API and that is incorporated as a significant structural fragment into the structure of the API. KSM can be an article of commerce, a material purchased from one or more suppliers under contract or commercial agreement or produced in-house. KSMs are normally of defined chemical properties and structures.



2.7 Formulation: Formulation means a finished dosage form of a drug product that contains one or more Active Pharmaceutical Ingredients (APIs) along with other pharmaceutical ingredients or excipients and is intended for administration to patients in forms such as tablets, capsules, solutions, injectables, ointments, suspensions, or other dosage forms.

2.8 Medical Device: Medical Device means any instrument, apparatus, appliance, implant, material or other article, whether used alone or in combination, including software or accessories, intended by its manufacturer to be used specifically for human beings or animals for one or more of the following purposes:

- diagnosis, prevention, monitoring, treatment or alleviation of any disease or disorder;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or disability;
- investigation, replacement, modification or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices; or
- providing information by means of in vitro examination of specimens derived from the human body.

A medical device does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but may be assisted in its intended function by such means.

Medical devices in India are regulated under the Medical Devices Rules, 2017, notified under the Drugs and Cosmetics Act, 1940, and administered by the Central Drugs Standard Control Organisation (CDSCO), as amended from time to time.

2.9 Pharmaceutical or Medical Device unit: any industrial entity engaged in manufacturing or production of pharmaceuticals (including key starting materials, drug intermediaries, bulk drugs, formulations etc.), biologics, biosimilars or medical devices.

2.10 Pharma/ Bulk Drug/ Medical Device Park: A cluster of Pharma/ Bulk Drugs/ Medical Devices and related ancillary manufacturing units developed over a minimum area of 10 - 25 acres based upon zone (low/medium/high/hyper potential zone) as per the existing norms of Town and Country Planning (TCP), Haryana and/or as amended from time to time.

The park should comprise of basic amenities such as internal roads, sewerage infrastructure, utilities infrastructure (electrical, water, natural gas, fire hydrants etc.), communication facilities, storage facilities, requisite technological infrastructure,



commercial infra etc. as necessary for the smooth functioning of units within the park. The park may also include common social infrastructure such as housing facilities, medical and sports facilities, banks, dormitories, recreational activities etc. and other enabling infrastructure such as Centre of Excellence (CoE), etc. and shall be developed and operated as per norms of Haryana Town and Country Planning Department (as amended from time to time)

- 2.11 Date of Commencement of Commercial Production/ Operations:** It means and refers to the date of first sale bill/invoice issued by the unit/enterprise. Only units/ enterprises commencing commercial operations during the validity period of this policy shall be eligible to avail benefits under this policy.
- 2.12 New Unit:** Refers to a unit established and commencing commercial production during the operative period of this policy.
- 2.13 Existing Unit:** Refers to any unit existing and in operation prior to notification of this policy.
- 2.14 Expansion/ Diversification:** Refers to investment undertaken by an existing unit at the same location for:
- i. enhancement of installed production or service capacity (or)
 - ii. upgradation, modernization, or technological improvement of existing plant, machinery, equipment, or processes (or)
 - iii. addition of new manufacturing or service lines (or)
 - iv. manufacturing of new or additional products; (or)
 - v. provision of new or additional services

An existing unit shall be eligible to avail incentives under this Policy for expansion/diversification undertaken at the same location, subject to fulfilment of any one of the following conditions:

- a. The unit undertakes an additional Fixed Capital Investment (FCI) of at least 50% of current FCI of the Project i.e. FCI as on date of commencement of expansion/ diversification
(or)
- b. The unit undertakes an additional FCI of at least 25% of current FCI of the Project i.e. FCI as on date of commencement of expansion/ diversification subject to a minimum expansion investment of INR 125 cr.
(or)



- c. The unit undertakes an additional FCI greater than the minimum threshold limit of Mega/ Ultra Mega Unit defined under this policy for the particular location.

Note: For the purposes of calculation of FCI in such cases, the original value of the assets shall be considered. Any existing unit undertaking expansion/ diversification at different locations shall be considered as a New Unit

11.1 Fixed Capital Investment (FCI): The new investment in land, infrastructure/ associated utilities, buildings (including for R&D activities, storage, testing, hostel/dormitories for workers, office space etc.), plant, machinery, equipment, power back up arrangements, construction of captive renewable energy plants, effluent treatment plants, waste management plants, air pollution control systems, zero liquid discharge equipment, hardware & software made by the unit within the premises of the project:

- during the policy period (and)
- before the commencement of commercial operations (and) 1 year after date of commencement of commercial production/ operations for MSME/Large units and 3 years after date of commencement of commercial production/ operations for Mega/ Ultra Mega Units or as decided by the Haryana Enterprises Promotion Board

shall be considered as Fixed Capital Investment (FCI)

Note:

- i. For the purposes of facilitating cases where investment has also been made prior to the notification of this policy but date of commencement of commercial production/operations falls under this policy period, the FCI made in the one-year period prior to the date of notification of this policy shall also be considered as FCI.
- ii. Transfer of plant, machinery and equipment from the same or different unit located anywhere else will not be considered towards calculation of FCI.
- iii. Working capital, goodwill, preliminary and pre-operative expenses, capitalized interest, and expenses incurred towards acquisition of technology or technical know-how, including consultancy charges, royalty, design and drawings, patents, licenses, and other intellectual property rights, whether capitalized in the books of accounts or otherwise, shall not be considered while calculating Fixed Capital Investment.

2.15 Ultra-Mega, Mega and Large Project: Projects shall be categorized as Ultra Mega, Mega and Large Projects as per definition in the Make in Haryana Industrial Policy of the State



as amended from time to time and/or any future flagship industrial policy of the State (if and when released).

2.16 Large Enterprises: Large Enterprises shall mean enterprises other than Micro, Small, and Medium Enterprises, having either:

- Investment in plant and machinery or equipment exceeding INR 125 crore, (or)
- Annual turnover exceeding INR 500 crore,

i.e., above the thresholds prescribed for Medium Enterprises under the Micro, Small and Medium Enterprises Development (MSMED) Act, 2006, as amended by the Government of India from time to time.

2.17 Medium Enterprise: Medium Enterprises shall mean enterprises where:

- Investment in plant and machinery or equipment does not exceed INR 125 crore, and
- Annual turnover does not exceed INR 500 crore,

in accordance with the thresholds notified by the Government of India under the MSMED Act, 2006, as amended from time to time.

2.18 Small Enterprise: Small Enterprises shall mean enterprises where:

- Investment in plant and machinery or equipment does not exceed INR 25 crore, and
- Annual turnover does not exceed INR 100 crore,

in accordance with the thresholds notified by the Government of India under the MSMED Act, 2006, as amended from time to time.

2.19 Micro Enterprise: Micro Enterprises shall mean enterprises where:

- Investment in plant and machinery or equipment does not exceed INR 2.5 crore, and
- Annual turnover does not exceed INR 10 crore,

in accordance with the thresholds notified by the Government of India under the MSMED Act, 2006, as amended from time to time.

2.20 Net SGST: Net SGST to be considered for reimbursement means that the eligible unit will be entitled to get reimbursement of SGST amount paid through cash ledger against the output liability of SGST on sale of eligible products. The eligible unit shall first have to utilize all the eligible Input Tax Credit (ITC) including eligible ITC of IGST available in its Credit Ledger, against the SGST output liability, before adjusting the SGST amount through Cash Ledger.



- 2.21 Local Employee:** An employee who is a bonafide resident of the State of Haryana (as defined by the Government of Haryana from time to time) will be considered a Local employee. The local employee status will only be verified using Parivar Pechan Patr issued by Government of Haryana
- 2.22 Category of Areas:** For promoting the geographical dispersal of industry, the State has been divided into 4 categories of Areas - Core Areas, Intermediate Areas, Sub-Prime Areas and Prime/Focus Areas based on their potential for industrial development. The classification of these areas shall be in accordance with the definitions prescribed under the Make in Haryana Industrial Policy of the State as amended from time to time and/or any future flagship industrial policy of the State (if and when released).
- 2.23 Eligible Startup:** Any entity shall be considered a startup if it meets the latest definition of startups as per the Haryana State Startup Policy 2022, as amended from time to time, and is registered with the Industries and Commerce Department, Haryana.
- 2.24 Centre of Excellence (CoE):** A Centre of Excellence (CoE) is a dedicated institutional or functional unit established to develop, anchor, and disseminate specialized capabilities in identified focus areas of the pharmaceutical and/or medical devices sectors. A CoE shall promote innovation, research and development, testing and validation, skilling and capacity building, and adoption of best practices, by bringing together industry, academia, research institutions, and domain experts in a collaborative framework.
- 2.25 Developer:** Developer means an individual, company, association, firm or a limited liability partnership, designated through a collaboration/development agreement with the owner for making an application for grant of licence and for completion of formalities required on behalf of such owner to develop a colony as per Haryana TCP Norms (as amended from time to time).
- 2.26 Owner:** Owner means a person or entity in whose name the title of ownership of land is vested, or in whose favour a valid lease of land for a period of not less than ninety-nine (99) years has been granted, within the State of Haryana, in accordance with the provisions of the Haryana Town and Country Planning (TCP) norms, as amended from time to time.



Policy Overview



3. Vision

“To transform Haryana into a globally competitive hub for pharmaceutical and medical devices manufacturing by fostering a robust, innovation-driven ecosystem.”

4. Mission

- i. To create a stable, enabling, and business-friendly environment for the manufacturing of pharmaceuticals and medical devices in the State.
- ii. To advance the ‘Make in India’ initiative by strengthening the entire healthcare value chain, reducing import dependence, and promoting indigenization of pharmaceutical and medical devices manufacturing.
- iii. To develop world-class industrial infrastructure and common facilities that support the growth, competitiveness, and sustainability of the pharmaceutical and medical devices ecosystem.
- iv. To foster continuous innovation and R&D, and encourage the development of advanced, affordable, and high-quality medical solutions, while ensuring adherence to stringent quality and regulatory standards.

5. Objectives

- i. To attract investments of at least INR 10,000 crore in the manufacturing of pharmaceuticals and medical devices within the State.
- ii. To generate a minimum of 20,000 direct and indirect employment opportunities across the pharmaceutical and medical devices sectors.
- iii. To reduce import dependence and promote exports from Haryana by enabling industry access to global markets through strengthened manufacturing capabilities, quality compliance, and export readiness.
- iv. To promote innovation, research, and development aimed at addressing technological gaps, enhancing product capabilities, and encouraging the development of advanced medical devices.

6. Validity of the Policy

This policy shall be valid for a period of 05 years from the date of notification of this policy or the date of any new policy/amendment, introduced by the Government of Haryana, whichever is earlier.



7. Eligibility Criteria

- 7.1 Units engaged in the manufacturing of Pharmaceutical products (including Active Pharmaceutical Ingredients, Key Starting Materials, Drug Intermediaries, Bulk Drugs, Formulations), Biologics, Biosimilars, Medical Devices and other related products etc. as defined by the Govt. of India (GoI) or as defined in any schemes/policies relating to pharmaceuticals/ medical devices sector issued by GoI from time to time shall be eligible under the policy.
- 7.2 The unit shall obtain and maintain all statutory approvals, registrations and licenses required for the manufacture, sale and distribution of pharmaceutical or medical device products, as applicable, under the Drugs and Cosmetics Act, 1940, the Drugs and Cosmetics Rules, 1945, and the Medical Devices Rules, 2017, as amended from time to time, or under any other relevant central or state laws and regulations in force
- 7.3 Only units which commence commercial production/ operations post the date of the notification of this policy and during the operative period of this policy will be eligible for availing benefits as enlisted under this policy.
- 7.4 Eligible units intending to avail incentives under this policy will be required to submit an application to the Department prior to the date of commencement of commercial operations
- 7.5 For the purposes of this policy, the Fixed Capital Investment (FCI) and Eligible Capital Expenditure (ECE) made:
- during the policy period (and)
 - before the commencement of commercial operations (and) 1 year after date of commencement of commercial production/ operations for Large units and 3 years after date of commencement of commercial production/ operations for Mega/ Ultra Mega Units or as decided by the Haryana Enterprises Promotion Board
- will be considered.
- Further, for the purposes of facilitating cases where investment has also been made prior to the date of notification of this policy, but date of commencement of commercial production/operations falls under this policy period, the FCI and ECE made in the one-year period prior to the date of notification of this policy will also be considered.
- 7.6 Existing Pharmaceutical and Medical Device Manufacturing units will also be eligible to avail incentives under this Policy for expansion/diversification undertaken at the same location, subject to fulfilment of the following conditions:
- Unit must be undertaking expansion/diversification anywhere in Haryana on land parcels with valid CLU permission (if applicable) under commercial or



industrial category or in Government-approved Industrial Estates / IMTs;
and

- (b) Unit must be undertaking an expansion/diversification, with either:
- an additional Fixed Capital Investment (FCI) of at least 50% of current FCI of the Project i.e. FCI as on date of commencement of expansion/ diversification

(or)
 - an additional FCI of at least 25% of current FCI of the Project i.e. FCI as on date of commencement of expansion/ diversification subject to a minimum expansion investment of INR 125 cr. (or)

(or)
 - an additional FCI greater than the minimum threshold limit of Mega/ Ultra Mega Unit defined under this policy for the particular location.

For the purposes of calculation of FCI in such cases, the original value of the assets shall be considered.

- (c) Unit must be commencing commercial production/ operations of said expansion/ diversification during the operative period of the policy.

Note:

- i. Units undertaking expansion/ diversification will be eligible for availing incentives for expansion/ diversification only once during the policy period.
- ii. In cases where expansion/diversification is undertaken through enhancement, upgradation, or modernization of existing production or service capacity, and where a clearly identifiable date of commencement of commercial production/operations cannot be determined:
 - Only investment made in the three-year period from the date of first expansion investment shall be considered as eligible investment period for the purpose of determination of FCI and ECE.
 - The date of completion of the entire committed capital investment for such expansion/diversification (or) the completion of 3 years from the date of first expansion investment, whichever is earlier, shall be



deemed to be the date of commencement of commercial production/operations for the purposes of this Policy.

- iii. Units undertaking expansion/ diversification will be required to obtain separate registration under GST for such expansion/diversification and maintain separate books of accounts for existing unit as well as the expanded unit. In case separate registration under GST is not feasible for a unit of expansion at the same business place, the highest turnover reflected by the existing unit in the last three years will be considered as the turnover of the existing unit for the purposes of estimation of different incentives. However, such a unit will also be required to maintain a separate book of accounts for the expansion unit, unless otherwise permitted by HEPB.

7.7 Units availing fiscal incentives under this policy shall not be eligible to avail or claim incentives for the same project under any other policy issued by the Government of Haryana, and vice versa, save and except for incentives under the Haryana Progressive MSME and Exports Policy, which may be availed only to the extent that such incentives are not covered under this policy under the same or a comparable head

7.8 The benefits offered under the policy will be over and above any incentives obtained under any Government of India policy or scheme by the eligible unit. However, the cumulative incentives under the policy to any Unit/ Park Developer, together with any fiscal incentives, subsidies, reimbursements, grants, or financial assistance received under any Government of India scheme for the same project, will be subject to a ceiling of 100% of Fixed Capital Investment (FCI).

8. Turnaround time under this policy

All new schemes/ operational guidelines proposed in the policy will be notified within a time frame of 03 months from the date of release of this policy. The fact that a scheme has not been notified shall not debar an investor whose application is consistent with the provisions of this policy from applying for and obtaining incentives under this policy.

Note: All the schemes to be notified under this policy shall be approved at the level of Administrative Secretary to Government, Haryana, Industries & Commerce Department and placed before the concerned Standing Finance Committee for approval and subsequent notification.



9. Authority for Clarification, Interpretation, and Operational Decisions

Administrative Secretary, Department of Industries and Commerce, Haryana will be the Competent Authority for clarification/resolution of any doubts related to the interpretation of any term or any provision arising under this policy, approval for notification of scheme operational guidelines for provisions under this policy and removal of difficulties for ease of doing business. The decision in this matter will be final and binding for all stakeholders in such cases.



Fiscal Incentives



10. Incentives for Pharmaceutical and Medical Devices Manufacturing Units

10.1 CAPEX and OPEX Support

S.No.	Incentive	Description of Support										
A.	CAPEX Support Incentive	<p>i. An eligible unit shall be entitled to reimbursement of a percentage of the eligible capital expenditure (CAPEX) incurred as shown in the table below, subject to a maximum ceiling of INR 200 crore per unit:</p> <table border="1"> <thead> <tr> <th>Area</th> <th>Eligible Reimbursement under CAPEX Support Incentive</th> </tr> </thead> <tbody> <tr> <td>Prime/Focus</td> <td>30% of eligible CAPEX</td> </tr> <tr> <td>Sub-Prime</td> <td>30% of eligible CAPEX</td> </tr> <tr> <td>Intermediate</td> <td>25% of eligible CAPEX</td> </tr> <tr> <td>Core</td> <td>20% of eligible CAPEX</td> </tr> </tbody> </table> <p>ii. For the purposes of this policy, eligible CAPEX shall include new investment/expenditure actually incurred and paid on account of the following:</p> <ol style="list-style-type: none"> Construction of building, infrastructure/ associated utilities and power backup arrangements Purchase of plant and machinery, equipment including tools, dies, molds, jigs, fixtures etc. used in the design, manufacturing, assembly, testing, packaging or processing of any of the goods eligible under the policy Purchase of IT hardware and software, including enterprise systems and other related items required for operations Construction of captive renewable energy projects (only new captive renewable energy projects ≥ 100 KW shall be eligible) Construction of Effluent Treatment Plant/ Waste Management Plant and installation of Air Pollution Control Systems Technology Acquisition from premier national/international institutes/ 	Area	Eligible Reimbursement under CAPEX Support Incentive	Prime/Focus	30% of eligible CAPEX	Sub-Prime	30% of eligible CAPEX	Intermediate	25% of eligible CAPEX	Core	20% of eligible CAPEX
Area	Eligible Reimbursement under CAPEX Support Incentive											
Prime/Focus	30% of eligible CAPEX											
Sub-Prime	30% of eligible CAPEX											
Intermediate	25% of eligible CAPEX											
Core	20% of eligible CAPEX											



S.No.	Incentive	Description of Support
		<p>domestic/foreign companies subject to a ceiling of INR 1 cr. per unit per year</p> <p>g. Payment of stamp duty on sale/ lease deeds for setting up unit/enterprise in the State</p> <p>h. Payment of external development charges</p> <p>iii. The CAPEX support incentive shall be disbursed in ten (10) annual instalments and shall commence after the date of commencement of operations or achievement of committed eligible capital investment, whichever is later subject to the time limits for recognition of Fixed Capital Investment/ Eligible Capital Expenditure specified under this policy.</p> <p>iv. Only the eligible CAPEX incurred during the:</p> <ul style="list-style-type: none"> • policy period (and) • before the commencement of commercial operations (and) <p>1 year after date of commencement of commercial production/ operations for MSME/Large units and 3 years after date of commencement of commercial production/ operations for Mega/ Ultra Mega Units or as decided by the Haryana Enterprises Promotion Board</p> <p>shall be considered.</p> <p>Additionally, for the purposes of facilitating cases where investment has also been made prior to the notification of this policy but date of commencement of commercial production/operations falls under this policy period, the eligible CAPEX made one year period prior to the date of notification of this policy shall also be considered.</p> <p><u>Note:</u> Transfer of machinery and equipment from the same or different unit located anywhere else will not be considered towards calculation of FCI.</p>



S.No.	Incentive	Description of Support										
B.	OPEX Support Incentive	<p>i. An eligible unit shall be entitled to reimbursement of a percentage of the eligible OPEX incurred as shown in the table below, for a period of ten years from the date of commencement of production/operations and subject to a maximum ceiling of INR 20 crores per annum per unit:</p> <table border="1"> <thead> <tr> <th>#</th> <th>Eligible Reimbursement under OPEX Support Incentive</th> </tr> </thead> <tbody> <tr> <td>Prime/Focus</td> <td>80% of eligible OPEX</td> </tr> <tr> <td>Sub-Prime</td> <td>70% of eligible OPEX</td> </tr> <tr> <td>Intermediate</td> <td>60% of eligible OPEX</td> </tr> <tr> <td>Core</td> <td>50% of eligible OPEX</td> </tr> </tbody> </table> <p>ii. For the purposes of this policy, eligible OPEX for a particular year shall include the actual expenditure incurred and paid by the unit on account of/on the following:</p> <ol style="list-style-type: none"> Net SGST paid to the Govt. of Haryana Electricity duty paid to the Govt. of Haryana Annual Lease rentals paid - shall be eligible @75% of actual annual rent paid by the unit and subject to an annual cap of 6% of the valuation of the property as assessed by a valuer registered under the Companies (Registered Valuers and Valuation) Rules, 2017, as amended from time to time Quality certification costs incurred towards obtaining nationally or internationally recognized quality certifications required for domestic sale or export of pharmaceutical and medical devices products such as ISO/ GMP/ CDSCO/ BIS/ USFDA/ DMF/ QSR/ PMA/ EMA/ QP/ CE/ WHO-GMP/ ZED/TS/ Hallmark certifications/ other standard industry certifications. Expenses incurred on Clinical Trials Expenses incurred on Bioavailability (BA) and Bioequivalence (BE) study subject to a maximum of 5 such studies in a financial year. 	#	Eligible Reimbursement under OPEX Support Incentive	Prime/Focus	80% of eligible OPEX	Sub-Prime	70% of eligible OPEX	Intermediate	60% of eligible OPEX	Core	50% of eligible OPEX
#	Eligible Reimbursement under OPEX Support Incentive											
Prime/Focus	80% of eligible OPEX											
Sub-Prime	70% of eligible OPEX											
Intermediate	60% of eligible OPEX											
Core	50% of eligible OPEX											



S.No.	Incentive	Description of Support
		<p>g. Patent related costs incurred towards filing of patents, consultancy charges, prior-art search fees, maintenance fees and publication fees</p> <p>h. Guarantee fee paid under Credit Guarantee Fund Trust for Micro and Small Enterprises (CGTMSE)</p> <p>i. Credit Rating Expenses - limited to ratings conducted by SEBI-accredited agencies (CRISIL, ICRA, CARE, SMERA, Fitch India, Brickwork Ratings) or SIDBI-empaneled agencies, as applicable.</p> <p>j. Freight charges (including insurance costs) incurred for exports - eligible @1% of Free on Board (FOB) value or actual export freight cost (excluding government fee and taxes on transportation of goods from place of manufacture to the seaport/ air cargo/ by road up to international border and including insurance cost), whichever is lower and subject to a maximum cap of INR 1 cr. per annum per unit</p>

Note:

Ultra Mega and Mega Projects shall also be eligible for customized packages of incentives by Haryana Enterprise Promotion Board (HEPB). This special package of incentives shall be decided by the Haryana Enterprise Promotion Board (HEPB) on a case-to-case basis and shall be offered over and above the standard package of incentives as per this policy and based on the approved Cost Benefit Analysis model of the State, as amended from time to time.

10.2 Incentives for Exports from Haryana

To promote and incentivize exports from the State of Haryana, eligible units shall have the option to avail export linked incentives under either of the following options, subject to the conditions specified herein. The unit shall be eligible to opt for only one of the options and such option, once exercised, shall be final and binding.

A. Option 1: CAPEX Support Linked Export Booster Incentive



Eligible units may opt to avail an additional Export Booster Incentive, which shall be provided as an enhancement to the CAPEX Support Incentive specified under Section 10.1 (A).

The quantum of such incentive shall be determined based on the proportion of exports in total sales during the first three (3) years from the Date of Commencement of Commercial Production/Operations (DoCP) and shall be calculated as follows:

$$\text{Export Booster (in \%)} = 5\% * [(\text{Proportion of Exports in Total Sales in \%}) - 10\%]$$

Note:

- i. Proportion of Exports in Total Sales = (Export-linked Cost of Goods Sold in first 3 years from DoCP)/ (Total Cost of Goods Sold in first three years from DoCP)
- ii. The Total Applicable Capital Subsidy Incentive shall be calculated as the sum of Eligible CAPEX Support Incentive under Section 10.1(A) + Export Booster Incentive as detailed above
- iii. The incentive shall be adjusted in the applicable quantum of capital investment incentive instalments.
- iv. Only units with minimum proportion of exports in total sales of 10% and a minimum average annual turnover of INR 100 cr. for the first three years from date of commencement of commercial production/ operations shall be eligible to avail this incentive.
- v. A Certificate of the Statutory Auditor certifying the details of export-linked Cost of Goods Sold (CoGS) and total CoGS for the given period shall be mandatory to avail this incentive

B. Option 2: Annual Export Turnover Linked Incentive

As an alternative to Option 1, eligible units may also opt for an annual export turnover-linked incentive as shown below:

$$\text{Annual Export Turnover Linked Incentive} = 3\% \text{ of annual export value}$$

Note:



- i. The Annual Export Turnover Linked Incentive shall be provided for a period of five years from the date of commencement of commercial production/ operations
- ii. The incentive shall be subject to an overall cap of 4.5% of Eligible Capital Expenditure
- iii. The incentive shall be disbursed annually based on actual export turnover achieved in the given financial year
- iv. A Certificate of the Statutory Auditor certifying the details of export-turnover for the relevant financial year shall be mandatory to avail this incentive

10.3 Incentives for Successful Commercialization of Patents Generated by the Unit

Type of Incentive	Quantum of Support
Domestic Patent Granted	INR 50 lakhs per successful patent application subject to overall cap of INR 5 cr. per unit over the policy period
International/ Foreign Patent Granted	INR 1 crore per successful patent application subject to overall cap of INR 10 cr. per unit over the policy period

Note:

- i. Only patents which have been successfully used commercially shall be eligible for benefits. Commercial application shall be verified through statutory auditor certification detailing the revenue generated/ efficiency obtained, etc. and should be backed by supporting documents such as product brochures or data sheets referencing the patented technology or technology transfer/licensing agreements referencing the technology and details as and if applicable
- ii. Only patents granted and used commercially during the period of the policy shall be eligible for benefits under this section.

10.4 Greening Incentives

Sustainability-linked incentives have been embedded in this policy to encourage and reward eco-friendly practices which reduce pollution and carbon footprints and improve



resource efficiency. The following incentives shall be granted for eligible green investments undertaken by eligible units:

Incentive	Quantum of Incentive	
	MSME/Large	Mega/ Ultra Mega
Carbon Credits Generated in the State	<p>Carbon Credits generated by an eligible unit from a project located within the State of Haryana during the validity period of the policy shall be eligible for an incentive of INR 100 per carbon credit unit, subject to an overall cap of INR 1 cr. per unit.</p> <p>Note:</p> <ul style="list-style-type: none"> • One (1) carbon credit unit shall represent one (1) metric tonne of carbon dioxide equivalent (tCO₂e) reduced, avoided, or removed. • Only carbon credits issued by the Bureau of Energy Efficiency (BEE) or internationally recognized carbon standard organizations such as Verra (VCS), The Gold Standard Foundation (Switzerland), Clean Development Mechanism (CDM), Global Carbon Council (Qatar), Plan Vivo, ART-TREES, or any other organization as decided by the Competent Authority shall be eligible 	
Establishment of Captive Renewable Energy Projects (≥ 100 kW)	INR 50 lakhs per MW, upto a maximum of INR 2.5 cr.	INR 50 lakhs per MW, upto a maximum of INR 10 cr.
Establishment of Zero Liquid Discharge (ZLD)	50% of the actual cost incurred for implementing the measure up-to a maximum of INR 5 cr. per unit subject to third party certification of adherence to discharge limits mandated by Haryana State Pollution Control Board as per relevant Central and State Government Acts	50% of the actual cost incurred for implementing the measure up-to a maximum of INR 10 cr. per unit subject to third party certification of adherence to discharge limits mandated by Haryana State Pollution Control Board as per relevant Central and State Government Acts
Green Certification from GRIHA, LEED, etc.	2% of the cost of the building, subject to a cap of INR 5 cr. per unit	

**Note:**

- i. Capital Expenditure incurred for the above initiatives shall not be included for estimation of eligible CAPEX for availing other incentives under the policy.
- ii. Rooftop solar panels or panels installed anywhere in the premises of the unit with a facility to store energy or operate under Net Metering mechanism (above 100 kW) generate energy (above 100 kW) will be considered for the purpose of Incentives for captive renewable energy
- iii. Reimbursement under the incentive for Green Certification from GRIHA, LEED, etc. shall be admissible only after the eligible unit has obtained the respective certification from the concerned certifying authority and submitted documentary proof thereof.

10.5 Human Resource Development Incentives:

S.No.	Incentive	Description of Support						
A.	Employment Generation and Capacity Building Subsidy	To reward local high-quality employment generation, a unit will be eligible to avail a local employment generation subsidy for a period of 10 years from Date of Commencement of Commercial Operations based upon the proportion of Haryana local employees in the workforce of the unit in a particular year as shown below: <table border="1" data-bbox="582 1305 1401 2004"> <thead> <tr> <th>Proportion of Haryana Local Employees in the Workforce in Particular Year</th> <th>Employment Generation Subsidy for General Category Haryana Local Employees</th> <th>Employment Generation Subsidy for Women/ SC/ Divyang / Agniveer/ Ex-Servicemen Category Haryana Local Employees</th> </tr> </thead> <tbody> <tr> <td>< 15%</td> <td>Not applicable</td> <td>Employment Generation Subsidy @120% of the average gross monthly salary will be provided for each eligible Women/ SC/ Divyang / Ex-</td> </tr> </tbody> </table>	Proportion of Haryana Local Employees in the Workforce in Particular Year	Employment Generation Subsidy for General Category Haryana Local Employees	Employment Generation Subsidy for Women/ SC/ Divyang / Agniveer/ Ex-Servicemen Category Haryana Local Employees	< 15%	Not applicable	Employment Generation Subsidy @120% of the average gross monthly salary will be provided for each eligible Women/ SC/ Divyang / Ex-
Proportion of Haryana Local Employees in the Workforce in Particular Year	Employment Generation Subsidy for General Category Haryana Local Employees	Employment Generation Subsidy for Women/ SC/ Divyang / Agniveer/ Ex-Servicemen Category Haryana Local Employees						
< 15%	Not applicable	Employment Generation Subsidy @120% of the average gross monthly salary will be provided for each eligible Women/ SC/ Divyang / Ex-						



S.No.	Incentive	Description of Support	
			Servicemen Category Haryana Local Employees subject to a cap of INR 1 lakh per year per employee
		≥15%	Employment Generation Subsidy @ {100%} + {20% * (Proportion of Haryana Local Employees in % - 15%)} of the average gross monthly salary will be provided for each eligible Haryana Local Employee subject to a cap of INR 1 lakh per year per employee
			Employment Generation Subsidy @ {120%} + {20% * (Proportion of Haryana Local Employees in % - 15%)} of the average gross monthly salary will be provided for each eligible Women/ SC/ Divyang / Ex-Servicemen Category Haryana Local Employees subject to a cap of INR 1.2 lakh per year per employee
		<p>Note:</p> <ul style="list-style-type: none"> i. Proportion of Haryana Local Employees = Total Haryana Local Employees of the Unit/ Total Employees of the Unit ii. Employment Generation Subsidy will be based on the proportion of Haryana local employees in the workforce in the given year. iii. This subsidy will be provided only for employees of Haryana who have been directly employed on payroll or on contract with ESI/PF Number for a period of at-least 1 year by the eligible unit. iv. This subsidy can be availed by an eligible unit for a period of 10 years from Date of Commencement of Commercial Operations 	



S.No.	Incentive	Description of Support
		<p>v. An employee who is a bonafide resident of the State of Haryana (as defined by the Government of Haryana from time to time) will be considered a Local employee. The local employee status will be verified only using Parivar Pechan Patr.</p> <p>vi. In cases where the average gross monthly salary of an eligible Haryana Local Employee is below INR 48,000, a minimum Employment Generation Subsidy of INR 48,000 per annum shall be provided to the unit per such employee for the relevant year.</p> <p>vii. For eligible expansion units, the subsidy will be available for incremental employee count beyond the count that existed before undertaking expansion</p>
B.	Employment Booster for Recruitment through HKRN	<p>i. In addition to the employment generation subsidy incentive mentioned above, units which recruit Haryana local employees through Haryana Kaushal Rozgar Nigam (HKRN) shall also be eligible to claim 100% reimbursement on the employer's statutory contribution under Employees' Provident Fund (EPF) for these employees for a period of 5 years. This incentive amount shall be subject to a ceiling of 12 per cent of the employee's basic salary plus applicable Dearness Allowance (DA) and retaining allowance, subject to a maximum limit of INR 25,000 per employee per year.</p> <p>ii. Further, based on details furnished by the unit, all such employees recruited through Haryana Kaushal Rozgar Nigam (HKRN) shall be reimbursed 100% of their employee's statutory contribution under Employees' Provident Fund (EPF) through Direct Benefit Transfer (DBT) for a period of 5 years. This incentive amount shall also be subject to a ceiling of 12 per cent of the employee's basic salary plus applicable Dearness Allowance (DA) and retaining allowance and subject to a maximum limit of INR 25,000 per employee per year.</p>



S.No.	Incentive	Description of Support
C.	Development of specialized courses in the Pharma/ Medical Devices Sector	In consultation with leading industry players, sector skill councils and academic institutions, focused and specialized skill development courses will be offered in State Skilling institutions, ITIs, Polytechnics and Pharma Colleges of Haryana to ensure ready availability of skilled workforce for the industry.
D.	Job Readiness Program	<p>i. The Government of Haryana shall facilitate partnerships between recognized academic institutions within the State and Pharmaceutical/ Medical Devices units to design and offer focused and specialized, industry-aligned courses, particularly for students in their final year or penultimate year, in line with the evolving requirements of the two sectors.</p> <p>ii. Pharmaceutical/ Medical Devices units shall be encouraged to offer internships/apprenticeships and to recruit students enrolled in such courses, thereby strengthening industry readiness and employability.</p> <p>iii. To incentivize Pharmaceutical/ Medical Devices units to provide internships/apprenticeships to such students, the State shall reimburse 50% of the stipend paid, subject to a ceiling of INR 15,000 per intern/apprentice per month, for a maximum duration of six (6) months per intern/apprentice, limited to fifty (50) interns/apprentices per unit per financial year. This reimbursement shall be over and above any similar support being provided under existing schemes or programs of the Government of India or the Government of Haryana.</p>



10.6 Special Incentives for Eligible Units:

S.No.	Incentive	Description of Support
1.	One-time support for shifting/relocating manufacturing facilities from outside Haryana	<p>i. For eligible units relocating their manufacturing operations to Haryana from an existing facility located outside Haryana, the Government of Haryana will provide a one-time relocation grant equal to 50% of the eligible relocation cost, subject to a maximum ceiling of:</p> <ul style="list-style-type: none"> • INR 5 crore per unit for relocation from a manufacturing facility located outside the State but within the country and • INR 10 crore per unit for relocation from a manufacturing facility located outside the country. <p>ii. For the purposes of this policy, eligible relocation cost will be limited to actual expenditure incurred and paid towards transportation and import of manufacturing plant, machinery and equipment from the existing location (whether within India or abroad) to the unit's manufacturing facility in Haryana, including:</p> <ul style="list-style-type: none"> • International and domestic freight charges; • Packing, handling, and insurance costs; and • Customs duties and import-related charges, as applicable. <p>iii. The grant will be one-time only and will be disbursed after commencement of commercial operations in Haryana, subject to verification by the competent authority</p>

10.7 Option to Avail Top-Up Support Under Different Government of India Schemes

Eligible Units commencing operations during the period of the policy and availing subsidy/incentives under Government of India's active Production Linked Incentive (PLI) schemes for the Pharmaceutical and Medical Devices Sector or other related flagship schemes or any new related programs/schemes which are launched by the Government of



India will have the option to avail an additional 50% top-up incentive on the benefits disbursed by Government of India during the policy period instead of the incentives described under section 10.1, 10.2, 10.3, 10.4, 10.5 and 10.6 of this policy. An eligible unit can choose to avail incentives only under either:

- i. Section 10.1, 10.2, 10.3, 10.4, 10.5 and 10.6 (or)
- ii. Section 10.7 of this policy

11. Special Incentives for Startup Units:

S.No.	Incentive	Description of Support
A.	Financial Assistance to Haryana Startups for Prototyping	<p>Eligible startups shall be entitled to reimbursement of seventy-five percent (75%) of the actual cost incurred for the development of product prototypes, subject to a maximum ceiling of INR 15 lakh per financial year per startup, with an allowance of up to two (2) prototype sanctions per financial year per startup.</p> <p>The reimbursement shall be subject to verification of eligible expenditure and such conditions as may be prescribed by the Department from time to time.</p>
B.	MedTech Pitch-A-thon	<p>The State Government shall organize MedTech-focused Pitch-A-Thons to identify, encourage, and support new, disruptive, and scalable technological innovations aimed at addressing key challenges faced by the medical devices industry and enabling the development of high-end, innovative products and solutions.</p> <p>Such initiatives shall promote the application of cutting-edge digital and advanced technologies, including Artificial Intelligence (AI), Machine Learning (ML), Data Analytics, Big Data, Internet of Things (IoT), Blockchain, and other emerging technologies, across the medical devices value chain.</p> <p>These Pitch-A-Thons shall foster innovation-led entrepreneurship, promote out-of-the-box thinking among startups and emerging entrepreneurs, and facilitate industry</p>



S.No.	Incentive	Description of Support
		linkages, mentoring, and potential commercialization opportunities.
C.	Bootcamp	<p>The Government of Haryana shall organize industry-specific bootcamps for stakeholders in the pharmaceutical and medical devices sectors to facilitate knowledge sharing, capability building, industry exposure, and identification of growth and investment opportunities.</p> <p>Such bootcamps may include participation from industry experts, academia, research institutions, startups, and regulatory bodies, and shall focus on emerging technologies, regulatory compliance, market access, and best industry practices.</p>

12. Other Support for Eligible Units:

S.No.	Incentive	Description of Support
A.	Industry Engagement & Outreach	To promote brand Haryana and attract private sector investments, the Government of Haryana shall organize focused conferences/ business events/ road shows and promotional events at various locations from time to time to facilitate B2B, B2G and G2G interactions.

13. Infrastructure Development Support

13.1 Incentives to Developers for Establishment of Private Pharmaceutical and Medical Devices Clusters/ Parks

To incentivize the development of private Pharmaceutical and Medical Devices Manufacturing Clusters and Parks at strategic locations in the State, the Government of Haryana shall provide fiscal support to such parks/clusters that obtain an industrial colony licence from the Town and Country Planning Department, Government of Haryana, and Consent to Establish (CTE) during the operational period of this policy, and



are developed in accordance with the prevailing norms of the Town and Country Planning Department. The fiscal support provided is as below:

13.1.1 Capital Subsidy or Net SGST Reimbursement Support Incentive

Eligible pharmaceutical and medical devices park/cluster developers shall be provided an option to choose between availing capital subsidy support or net SGST reimbursement support as showcased below.

A. Option 1: Capital Subsidy Support

S.No.	Area Category	Percentage of financial assistance (reimbursement as a % of eligible capital expenditure)
1.	Sub-Prime	75%
2.	Prime/Focus Areas	85%

Note: Any land/area granted an industrial colony license by the Town and Country Planning Department after the notification of this policy shall be treated as a Sub-Prime Area.

Eligible capital expenditure will include the cost incurred for the development of trunk infrastructure/ associated utilities such as internal roads, power generation/distribution system, power back-up systems, water treatment plant, sewerage treatment plant/ common effluent treatment plant, utility tunnels, requisite technological and communication infrastructure, ready-built factories/sheds, etc., required for the smooth functioning of units within the park. The maximum assistance offered by the Govt. of Haryana will be capped at a ceiling of INR 45 Crores per park.

Further, this incentive will be disbursed in tranches, based on completion and occupancy as shown below:

Instalment	Criteria	Grant Tranche
First Instalment	On grant of requisite license for development of the park and Development of the park with requisite amenities as per approved development plan and grant of completion by Department of Town and Country Planning	50% of Eligible Incentive
Second Instalment	Proof of operation of at least 25% of total permissible area earmarked for setting up units as per approved development plan.	20% of Eligible Incentive



Instalment	Criteria	Grant Tranche
Third Instalment	Proof of operation of at least 50% of total permissible area earmarked for setting up units as per approved development plan.	15% of Eligible Incentive
Fourth Instalment	Proof of operation of at least 75% of total permissible area earmarked for setting up units as per approved development plan.	15% of Eligible Incentive

B. Option 2: SGST Reimbursement Support

Eligible Developers may also choose to avail Net SGST reimbursement on the expenditure incurred towards the development of trunk infrastructure/ associated utilities such as internal roads, power generation/distribution system, captive renewable energy plants, power back-up systems, water treatment plant, sewerage treatment plant/ common effluent treatment plant, utility tunnels, requisite technological and communication infrastructure, ready-built factories/ sheds, etc., required for the smooth functioning of units within the park for a period of five years from the date of obtaining Consent to Establish (CTE) and subject to an overall cap of INR 45 crore per park. The Net SGST reimbursement shall be provided at the following rates:

Area	Quantum of Net SGST Reimbursement
Sub-Prime Area	60% reimbursement for 7 years
Prime/Focus Area	70% reimbursement for 7 years

Note: Any land/area granted an industrial colony license by the Town and Country Planning Department after the notification of this policy shall be treated as a Sub-Prime Area

13.1.2 Stamp Duty Reimbursement

100% of the Stamp Duty paid by the developer for parks being developed in Sub-Prime and Prime/Focus Areas shall be reimbursed upon obtaining of requisite license for development of the industrial park and CTE during the policy period, irrespective of the period in which the land was purchased.

13.2 Support for establishing R&D Centers in Pharmaceutical and Medical Devices Sector

a. Capital Subsidy:

- i. Financial assistance equal to 50% of the eligible capital cost incurred will be provided to new and existing Pharmaceutical and Medical Devices Sector



units establishing R&D Centres for research and innovation anywhere in the State, subject to the following ceilings:

- Up to INR 50 crore per R&D centre for Ultra Mega Projects.
- Up to INR 25 crore per R&D centre for Mega R&D Projects.
- Up to INR 10 crore per R&D centre for all other R&D Projects

- ii. Eligible capital cost will include expenditure actually incurred on infrastructure and associated utilities (excluding land), buildings, plant and machinery, equipment, power backup arrangements, IT hardware and software, and other capital assets directly required for the R&D facility. Working capital, goodwill, preliminary and pre-operative expenses, capitalized interest, and expenses incurred towards acquisition of technology or technical know-how including consultancy charges, royalty, design and drawings, patents, licenses, and other intellectual property rights, whether capitalized in the books of accounts or otherwise, shall not be considered while calculating total capital cost
- iii. The capital subsidy will be disbursed in five (5) annual instalments, subject to verification by the competent authority.
- iv. Taking into account the time required for grant of recognition by DSIR/CSIR, an eligible unit may apply for incentives under this section within a period of 3 years from date of commencement of operations of the R&D unit.

- b. **Operational Subsidy:** Financial assistance will also be provided in the form of reimbursement of 50% of the eligible operating expenditure incurred for running the R&D Centre, subject to a maximum ceiling of INR 2 crore per R&D centre per year, for a period of five (5) years.

Eligible operating expenditure will be limited to costs incurred on:

- i. Salaries of scientists, engineers, and research personnel;
- ii. Participation in conferences, seminars, and workshops;
- iii. Fees associated with publication of research papers; and
- iv. Raw materials, consumables, components, and other inputs directly required for research activities.

Note:

- The support for establishing R&D centers will be limited to 5 R&D centers established by new or existing pharmaceutical and medical device manufacturing



units located in Haryana subject to the R&D center being recognized by the Department of Scientific & Industrial Research (DSIR) or Council of Scientific & Industrial Research (CSIR).

Simplified Regulatory Regime





14. Simplified Regulatory Regime

In its endeavour to create a conducive business climate for the Pharmaceutical and Medical Devices sector, the Government of Haryana has implemented the following reforms for regulatory simplification, improving the Ease of Doing Business in the State and ensuring a hassle-free experience for the investor.

14.1 Constitution of Haryana Enterprise Promotion Centre for promotion of Ease of Doing Business

The Government of Haryana has established the Haryana Enterprise Promotion Centre (HEPC) as a dedicated nodal agency under the Haryana Enterprises Promotion Act, 2016 (HEPA) to facilitate and promote ease of doing business in the State. Operating as a single-roof clearance mechanism, HEPC streamlines the process of obtaining clearances, approvals and licenses required by businesses and investors to set up and operate enterprises in Haryana.

14.2 Invest Haryana Single Window Portal

The Government of Haryana has developed the Invest Haryana Single Window Portal as an integrated online platform to simplify and expedite the process of setting up businesses in Haryana. This portal serves as a one-stop digital interface to streamline regulatory processes and ensure ease of access to over 140 business related services, ensuring transparency, reduced paperwork, and minimization of delays by providing a seamless, end-to-end service experience.

14.3 Timebound Clearances for All Services

The Government has laid down clearly defined timelines for delivery of services on the Invest Haryana Single Window Portal. The Government shall ensure that approvals for all services are granted within the timelines specified.

14.4 Dedicated Sectoral Relationship Managers for Handholding and Investment Facilitation Support

Dedicated relationship managers shall be assigned for every ultra mega, mega and large investor to provide dedicated handholding and investment facilitation support.

14.5 Self-Certification and Third-Party Certification

The Government of Haryana has allowed Self-certification vide Notification No. 11/12/2018-4Lab dated 03.05.2018 (as amended from time to time), for Labour related clearances and approvals under 14 acts of the Labour Department in Haryana as shown below:

- Factories Act, 1948 and Rules framed thereunder.
- Minimum Wages Act, 1948 and Rules framed thereunder.
- Payment of Wages Act, 1936 and Rules framed thereunder.



- Contract Labour (Regulation & Abolition) Act, 1970 and Rules framed thereunder.
- Payment of Bonus Act. 1965 and Rules framed thereunder.
- Payment of Gratuity Act, 1972 and Rules framed thereunder.
- Maternity Benefit Act, 1961 and Rules framed thereunder.
- Child Labour (Prohibition & Regulation) Act, and Rules framed thereunder.
- Shops & Commercial Establishments Act, 1958 and Rules framed thereunder.
- The Inter-State Migrant Workmen (RECS) Act, 1979 and Rules framed thereunder.
- The Equal Remuneration Act, 1976 and Rules framed thereunder.
- Motor Transport Workers Act, 1961 and Rules framed thereunder.
- Punjab Industrial Establishments (National & Festival Holidays & Casual and Sick Leave) Act, 1965.
- The Building and Other Construction Works (Regulation of Employment and Conditions of Service) Act, 1996

The Government of Haryana has also notified 3rd Party Certification/ Audit Scheme (Amendment), 2018 vide Notification No. 11/13/2018-4Lab dated 03.05.2018 (as amended from time to time) to facilitate entrepreneurs for complying with the provisions of Factories Act, 1948 and rules framed there-under.

14.6 Online single return for various Acts pertaining to the Department of Labour

The Labour Department has implemented the online submission of a unified single return under all labour laws.

14.7 Allowing three shifts and night shifts for Women

Pharmaceutical and Medical Devices Units shall be permitted three shift operations allowing women to work at night, subject to the units taking the necessary precautions with respect to the safety and security of women employees. In addition, the government will implement an auto-renewal system, basis self-certification for such permissions (subject to fulfilling necessary regulatory compliance) and encourage faceless and paperless approval.

14.8 Essential Services

The Government shall declare Pharmaceutical and Medical Devices Units (as covered under this policy) as an essential service under Haryana Essential Services Maintenance Act, 1974. The eligibility for such units will be decided by the Steering Committee.



14.9 Compliances Reduction and Deregulation

The Government of Haryana has undertaken the following key reforms to simplify and consolidate regulatory processes, remove duplicative licensing requirements and expedite approvals at both the establishment and operational stages of businesses:

- To provide flexibility to developers, the Government shall promote mixed land use in new master plans, with a particular focus on Transit Oriented Development (TOD) zones
- The State has introduced a prohibited list of activities under the Mixed Land Use category in the Development Plans. All activities, except those explicitly included in the prohibited list, shall be considered permissible, subject to compliance with the prevailing policy parameters.
- Third-party certification have been introduced for granting Consent to Operate (CTO) to Green category industries (other than MSMEs). For MSMEs in the Green category, CTO through self-certification has been allowed.
- The State has reduced timelines from 30 working days to 21 working days for providing Consent to Establish and Consent to Operate.
- The State has expanded the list of White Category Industries to 734 incorporating the recent changes in the White Category list issued by CPCB.
- A provision for instant automated CLU approval has been introduced in designated industrial zones and the documentation required to obtain Change of Land Use (CLU) approval has been streamlined to only three essential documents - the ownership document, the project report, and the indemnity bond.
- The area requirement for establishing industries has been completely waived.
- The State has removed earlier restrictions that prohibited women from working in certain hazardous industries.
- The State has allowed the industries on 20 ft. (6m) wide village link roads also in the agriculture/rural zone and industrial units in agriculture zone having direct access from Schedule Road, National Highway and State Highway.
- Clearances for obtaining utilities such as electricity and water connections have been fully integrated into the Invest Haryana Portal.
- The threshold under the Haryana Shops and Commercial Establishment Act, 1958 has been increased from 0 to 20 workers, thereby reducing compliance obligations for smaller establishments.



- The State has also increased daily working hours from 9 to 10 and weekly quarterly overtime upto 156 hours.
- The Haryana Building Code has been amended in line with global best practices to allow for unrestricted FAR, unrestricted Ground Coverage and unrestricted Maximum Permissible Height have been permitted subject to fulfilment of fire safety, structural safety, light & ventilation and parking norms as specified in the code and payment of fees/ charges as applicable.
- The Haryana Building Code has also been amended to allow third-party agencies to grant Occupation Certificates for high-risk buildings.

14.10 Timely Processing of Incentive Applications:

To enhance transparency, certainty, and timeliness in the processing and disbursement of incentives, the State Government shall ensure upfront release of fifty percent (50%) of the eligible incentive amount after preliminary scrutiny of the incentive claim within seven (7) working days from the date of submission of the application. The remaining fifty percent (50%) of the eligible incentive shall thereafter be disbursed within forty-five (45) working days from the date of application after detailed scrutiny of applications.

The timeliness of incentive processing and disbursement shall be tracked through the Invest Haryana Single Window Portal. In case of any delay purely attributable to the concerned Department, interest at the rate of 8% per annum, or such different rate as may be notified by the Government from time to time, shall be payable on the delayed incentive amount.

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

The Government of Haryana shall accord approval to all drug formulations that have received authorization from the licensing authorities of neighbouring States or have been categorized as 'rational' by expert committees constituted by the Government of India, within 7 working days of the date of application on the portal of the Department provided such products are not banned or prohibited by the Government of India under Section 26-A of the Drugs and Cosmetics Act.

14.12 Simplification of tender processes

The Government of Haryana shall streamline tender participation procedures by enabling the online issuance of tender participation certificates within a defined turnaround time of seven (7) working days. This service shall be integrated with the State's Single Window System and shall include provisions for e-signatures by the designated authorities to ensure timely, transparent, and efficient processing



14.13 Steering Committee

A Steering Committee under the chairmanship of Administrative Secretary, Industries & Commerce, Haryana and comprising senior officials from concerned departments, Industry Experts/ Associations, or any other special invitee, etc. will be formed for deliberation on policy matters and implementation thereof.

Note: All the eligible Pharmaceutical and Medical Devices units shall be given the above regulatory benefits in addition to the ones mentioned in the Make in Haryana Industrial Policy (as amended from time to time) or any new Industrial Policy of the State.



Annexure-I Indicative list of Medical Devices Covered under the Policy

S.No.	Sector	Medical Device Components
1	Implantable Medical Devices	Cardiac stents, drug eluting stents, heart valves, pacemakers, orthopaedic implants, artificial joints, intra-ocular lenses (IOL), internal prosthetic replacements
2	Medical Disposables	Syringes, needles, IV cannulae, catheters, scalp vein sets, surgical gloves, blood bags, sutures, medical dressings, dialyser, membrane
3	Diagnostic Medical Devices	Stethoscopes, blood pressure monitors, thermometers, pulse oximeters, diagnostic test kits
4	In-Vitro Diagnostic (IVD) Devices	Clinical chemistry analyzers, immunology devices, haematology devices, microbiology devices, molecular diagnostic systems, urinalysis devices, serology tests, genetic testing devices, sample collection tubes and containers
5	Electro-Medical Equipment	Electrocardiographs (ECG), EEG monitors, patient monitoring systems, defibrillators, ventilators, anaesthesia machines
6	Imaging and Radiology Equipment	Ultrasound systems, CT scanners, MRI systems, radiography equipment, digital subtraction angiography systems
7	Surgical and Endoscopic Devices	Surgical instruments, laparoscopes, endoscopes, colonoscopes, surgical microscopes, surgical diathermy units
8	Operation Theatre Equipment	Surgical tables, operating lights, suction machines, anaesthesia workstations, surgical monitoring systems
9	Rehabilitation and Assistive Devices	Wheelchairs, mobility aids, walkers, crutches, hearing aids
10	Components and Accessories	Medical device components such as sensors, tubing, connectors, implant components, electronic modules and other accessories used in medical devices
11	Any other medical device or related component as may be notified by the Government of India from time to time	