

Sectoral

Medical devices

1. What is the regulatory environment for medical devices in India as per 'New Medical Devices Rules'?

The Ministry of Health and Family Welfare on Thursday notified Medical Devices Rules, 2017, which are in conformity with Global Harmonisation Task Force (GHTF) framework. The rules have come into effect from 1 January 2018. The rules have been drafted with the intention to distinguish medical devices from pharmaceuticals for improved and well-defined regulation. The key highlights of the rules are: 1) Redefining ' medical devices ', making it more comprehensive and easy to comprehend. 2) Introduction of risk-based classification system for class-wise regulation. 3) Single window clearance (online portal) for applications for import, manufacture, sale or distribution and clinical investigation. 4) Establishment of product standards for medical devices for being conformed. 5) Rationalization of timelines for obtaining licenses required to market medical devices. 6) Consolidation of registration certificate and import license into a single license. 7) New regulatory framework for clinical investigation of medical device.

2. What are the requirements to be a registered Notified body?

The requirements are laid down in Part I of Third Schedule of Medical Devices Rules, 2017.

3. What is the process for classification verification with CDSCO or notified body prior to submission?

The Central Licensing Authority shall, classify medical devices referred to in Rule 2, based on their intended use and other parameters specified in the First Schedule. Based on the classification referred to in sub-rule (3), class wise list of medical devices shall be published on the website of the Central Drugs Standard Control Organization (CDSCO): Provided that the Central Licensing Authority may, from time to time, make additions or deletions in such list of medical devices or modify the class of any medical device. CDSCO has already displayed the list of medical devices with classification, which is dynamic in nature.

4. What are the changes that require an applicant to make a fresh Registration?

The following changes require a fresh registration: 1) Any change with respect to manufacturer (legal/actual) like change in constitution, change in name, change in address, etc. 2) Any change with respect to importer/Indian Agent like change in constitution, change in name, etc.

5. How are IVDs classified in India under Medical Device Rules, 2017? Who will have the responsibility of doing Classification of IVD as per Class A/B/C/D?

IVDs are classified under Chapter II, Rule 4, Sub-rule (2) of Medical Device Rules, 2017 on the basis of parameters specified in Part II of the First Schedule, in the following classes, namely: i) Low risk - Class A, ii) Low moderate risk- Class B. iii) Moderate high risk- Class C. iv) High risk- Class D. Reference Rule 4 (3): This rule specifies that Central Licensing Authority shall classify the Medical Devices.

6. How much FDI is permitted under medical devices sector?

100% FDI is permitted under medical devices sector through automatic route.

7. If a company misses a threshold (investment / incremental sale) in one year but compensates for that in the next year by having met the total cumulative figure – Then will the company be eligible for the missed incentive?

In case an applicant does not meet minimum threshold criteria for any given year, the applicant shall not be eligible for disbursement of incentive for that particular year. However, the applicant will not be restricted from claiming incentive for subsequent years during the tenure of the Scheme, provided eligibility criteria are met for such subsequent years.

8. Is assembly of products considered to be ' Manufacturing ' under the scheme?

All activities applicable under the Central Goods and Service Tax 2017 definition of 'Manufacturing' will be eligible under the PLI scheme for incentives. (refer scheme guidelines for more information).

9. What are the eligible Investments, that will be calculated for the threshold Investment?

The investments that are eligible for the threshold investment calculation are: Expenditure incurred on new Plant, Machinery, Equipment and Associated Utilities Eligible investment includes expenditure on a new plant, machinery, equipment and associated utilities as well as tools, dies, moulds, jigs, fixtures (including parts, accessories, components, and spares thereof) of the same, used in the design, manufacturing, assembly, testing, packaging or processing of any of manufactured goods covered under target segments. Expenditure incurred on new Research and Development (R&D) Eligible investment includes capital expenditure on R&D and product development related to Target Segments. Expenditure related to Transfer of Technology (ToT) Agreements Eligible investment includes the cost of technology and initial technology purchase related to manufactured goods covered under Target Segments. Associated Utilities Expenditure incurred on associated utilities as defined in the scheme guideline shall be considered as Investment for determining eligibility under the Scheme. (refer scheme guidelines for more information)

10. Will used machinery be allowed under the calculated Investment under the threshold Investment?

Used / Refurbished machinery will not be counted in the investment calculation under the threshold.

11. How are the applications for the scheme to be submitted?

All applications will be submitted through an online portal maintained by the Project Management Agency (PMA). In case, the portal is not available; applications may be submitted in physical form to the PMA. The URL of the online portal will be made available on the website of the DoP.

12. How will the incentive be calculated?

The incentive applicable for a selected applicant will be computed as follows: Net Incremental Sales of Eligible Product(s) x Rate of Incentive Where: Eligible Product(s) means the products stated in the approval letter. Incremental Sales shall be Net Sales Turnover of Eligible Product(s) for the period of which claim for disbursement of incentive pertains minus the Net Sales Turnover of said Eligible Product(s) for the base year. In case of return of Sales of Eligible Product(s), the Gross Sales Turnover shall be reduced by the amount corresponding to such return of sales. If the corresponding sales

have been considered for claim processing for the earlier period, the sales return shall be adjusted with Gross Sales Turnover for the period in which the actual sales return takes place. Rate of incentive: 5%

13. What is the evaluation Criteria for selection of company under the PLI Scheme?

Score will be given to a company based on 5 factors including manufacturing turnover, Existing Patent / Technology transfer, Existing ISO 13485, Average R & D expenses, and Regulatory approval. Applicants will be selected basis the score. (refer scheme guidelines for more information).

14. Will exports be counted in the Incremental sale calculation?

Exports of the Eligible Product(s) stated in the approval letter will be counted in the Incremental sale calculation.

15. Will brownfield projects be eligible under the scheme?

No only Greenfield as per the scheme definition are eligible for the Production Linked Incentive scheme for Medical Devices. (refer scheme guidelines for more information).

16. Can an Applicant apply for incentives under the scheme in multiple target segments?

There shall be no restriction on any applicant applying in more than one target segment. However, the applicant shall be required to submit a separate application along with the application fee for each target segment and shall be required to separately meet the eligibility criteria of threshold Investment and Incremental Sales of Manufactured Goods for each application.

17. Is the list of common facilities applicable in the scheme exhaustive?

The list of common facilities/center given in the list are indicative and states are encouraged to plan for facilities, the implementing agency considers useful.

18. How will funds for the Medical Parks be disbursed?

Grant-in-aid will be released in four instalments in the following manner: Installment Percentage of Funds Remarks/ Pre-requisites First 30 On final approval of the project by the SSC and after the deposit of 30% of SIA's share in the project cost in the Trust and Retention Account (TRA) or Escrow or No Lien Account as the case may be, subject to the condition that all relevant environment clearances are in place. Second 30 60% utilisation of the first instalment and after the proportionate expenditure has been incurred by the SIA with proportionate physical progress of the Medical Device Park as per the DPR. Third 30 100% utilisation of first instalment and at least 60% utilization of second instalment and after the proportionate expenditure has been incurred by the SIA with proportionate physical progress of the Medical Device Park as per the DPR. Fourth 30 100% utilisation of second and third instalments and SIA has mobilized and spent its entire share in proportion to the grant and completed the project in all respects.

19. Who will be responsible for Maintenance of Assets?

State Implementation Agency shall be responsible for Operation and Management of assets created under the Scheme.

20. Will grants be applicable for investment for construction of roads, buildings, etc.?

No grant shall be given towards construction of roads, compound wall and buildings. However, as far as various scientific facilities/ centres are concerned, 30% of the estimated cost of the respective facility/ centre will be allowed from grant-in-aid towards the construction of the building.

21. Who are all the responsible authorities for the Scheme?

Project Management Agency (PMA) Project Management Agency (PMA) will be nominated by Department of Pharmaceuticals for providing secretarial, managerial and implementation support to DoP for effective implementation of the Scheme. Technical Committee (TC) Technical Committee, constituted by the DoP and experts having knowledge and experience in regulations, manufacturing of medical devices and R&D of medical devices will assist in technical matters referred to by the DoP & SSC. State Implementing Agency (State Implementation Agency) State Implementing Agency (SIA), a legal entity shall be set up by the State Government to implement the Medical Device Park Project. Scheme Steering Committee (SSC): Proposals under the Scheme will be approved by the Scheme Steering Committee (SSC). The committee will comprise of: Secretary, DoP - Chairperson Financial Adviser, DoP - Member Joint Secretary, Ministry of Environment, Forest and Climate Change

-Member Joint Secretary, Department for Promotion of Industry and Internal Trade -Member Joint Secretary, Department of Health and Family Welfare — Member DCGI, Central Drug Standard Control Organization - Member Joint Secretary (Policy), DoP - Convenor State Government Responsible for the submission of the Project Report and other information pertaining to the Medical Device Parks.

22. What is the evaluation Criteria for selection of state under the Parks Scheme?

Score will be given to a state based on 11 parameters. The top 4 states will be selected for incentives under the parks scheme. The Evaluation Criteria is as follows:

S. No.	Parameter	Maximum Marks
1	Utility charges	25
2	State Incentive Infrastructure	12
3	Connectivity of the Park	12
4	Lease rate	10
5	Total area of the proposed park	10
6	Uninterrupted 24*7 availability	7
7	Stamp Duty and Registration charges	5
8	Ease of Doing Business Ranking of the State	5
9	Availability of Technical Manpower	5
10	Presence of Institutes for technology transfer	5
11	Industrial Network	4

23. What does the notification called the Indian Medicine Central Council (Post Graduate Ayurveda Education) Amendment Regulations, 2020 deal with?

The notification relates to the Shalya and Shalakya streams of Post Graduate Education in Ayurveda. The notification specifies (in clearer terms than the earlier notification on the subject) a total of 58 surgical procedures that PG scholars of these streams (cumulatively) need to be practically trained in so as to enable them to independently perform the said activities after completion of their PG Degree. The notification is specific to these specified surgical procedures and does not allow Shalya and Shalakya Post Graduates to take up any other types of surgery.

24. What is the tenure of the PLI Scheme for Medical Devices?

The tenure of the PLI Scheme for Medical Devices shall be from FY 2020-21 to FY 2027-28 The tenure of the PLI Scheme for Pharmaceuticals (with focus on in-vitro diagnostic devices) shall be from FY 2020-21 to FY 2028-29