DEPARTMENT OF PHARMACEUTICALS

Medical devices PLI extended to FY 2035-36, fresh applications invited

New PLI guidelines for medical devices run the scheme to FY 2035-36 and invite fresh applications, with incentives of 3% to 10% of incremental sales.

THE DEPARTMENT OF Pharmaceuticals (DoP) has issued new guidelines for the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, under File No. 31026/19/2020-MD, dated November 10, 2026, signed by Aman Sharma, Joint Secretary. They extend the scheme up to FY 2035-36 and say fresh applications will be invited. They replace the scheme's earlier guidelines of July 27, 2020, October 29, 2020, August 18, 2022, February 25, 2023, December 19, 2023 and March 12, 2024. The scheme itself was approved on March 20, 2020 and notified by Gazette Notification No. 31026/08/2020-MD of July 21, 2020.

KEY FACTS

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Guidelines for the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, File No. 31026/19/2020-MD

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Department of Pharmaceuticals · November 10, 2026

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Any company or limited liability partnership registered in India with a positive net worth (counting its group companies) can apply, unless a bank or financial institution has declared it bankrupt, a willful defaulter or a defaulter, or reported it as a fraud. There are four target segments: TS1, consumables, disposables and implants; TS2, critical components used to make medical devices; TS3, high-end devices whose domestic manufacture is at a nascent stage; and TS4, high-end devices that are only assembled in India. Annexure 1A lists indicative products in each, and the Empowered Committee, chaired by the CEO of NITI Aayog, can approve products outside the lists.

Projects must be greenfield, except in TS4, where the incentive pays for deeper value chain integration instead. In TS1, TS3 and TS4, an applicant whose average annual turnover over the last three years is below Rs 150 crore must invest at least Rs 50 crore; at Rs 150 crore or more there is no minimum, and TS2 has none at all. Investment counts from April 1, 2026 and covers new plant, machinery, equipment and utilities, R&D, and technology bought from an unrelated party; land and buildings don't count. Clinical trials in India can count for up to 10% of committed investment.

The incentive is a percentage of incremental sales of the approved products over five performance years, after up to three years to set up the plant. No segment has a minimum sales threshold. TS1 pays 7%, 7%, 4%, 3% and 3%, needs 10% CAGR in sales, and needs approval from a stringent regulatory authority country (USA, EU, Canada, Japan, Australia, Switzerland and UK) with sales there. TS2 and TS3 pay 7%, 7%, 7%, 5% and 3% even if the committed value chain integration isn't met, plus another 3% for the whole period once it is, which makes 10%, 10%, 10%, 8% and 6%. TS2 needs sales growth of 2%, 3%, 4% and 5% in years 2 to 5 over year 1; TS3 needs none, but its value chain integration is mandatory. TS4 pays 7%, 7%, 7%, 5% and 4%, and nothing until the committed value chain integration, measured on the bill of materials, is achieved by the end of the fifth year. There is no ceiling per applicant or group.

About Rs 2,700 crore of the scheme's Rs 3,420 crore approved outlay remains. It is split into yearly incentive budgets for the 2nd to 8th scheme years: Rs 150, 250, 500, 600, 700, 300 and 200 crore. When eligible claims exceed the money available in a half year, the incentive is paid pro rata and the shortfall carries forward.

Applications go online through the Project Management Agency's portal, which needs an Entity Locker ID, with a non-refundable fee of Rs 1,00,000 each. The window opens on a notice on DoP's website and stays open, with applications received by the last day of each month taken up together. An applicant can file any number of applications in each target segment, with a separate application for each segment, and applications are to be finalized within 60 days of being taken from the portal. A selected applicant gives a bank guarantee of Rs 30 lakh per application within three weeks of approval, invoked if it hasn't put in at least 50% of the committed investment within three years.

Claims are filed twice a year, within three months of the end of each half of the financial year. A claim backed by audited accounts is paid in full; one backed by management-certified statements is paid 80%, with the other 20% released after audited statements arrive by October 15. Components a company uses in its own devices earn nothing; only sales to third parties count.

Issued by	Department of Pharmaceuticals, Ministry of Chemicals and Fertilizers
Document	Guidelines for the Production Linked Incentive (PLI) Scheme for Promoting Domestic Manufacturing of Medical Devices, File No. 31026/19/2020-MD
Dated	November 10, 2026
Signed by	Aman Sharma, Joint Secretary
Scheme runs to	FY 2035-36, with up to three years of gestation and up to five performance years
Who can apply	Companies and LLPs registered in India with positive net worth
Target segments	TS1 consumables, disposables and implants; TS2 critical components; TS3 high-end devices at a nascent stage of domestic manufacture; TS4 high-end devices only assembled in India
Minimum investment	Rs 50 crore in TS1, TS3 and TS4 for applicants with average annual turnover below Rs 150 crore; none at Rs 150 crore or more, and none in TS2
Investment cut-off date	April 1, 2026
Remaining outlay	About Rs 2,700 crore of Rs 3,420 crore approved
Application fee	Rs 1,00,000 per application, non-refundable
Bank guarantee	Rs 30 lakh per application, within three weeks of approval
Application window	Opens on a notice on DoP's website; applications taken up at the end of each month

Replaces	Guidelines of July 27, 2020, October 29, 2020, August 18, 2022, February 25, 2023, December 19, 2023 and March 12, 2024

Incentive and conditions by target segment (Annexures 2 and 3)

Target segment	Incentive on incremental sales, years 1 to 5	Sales growth	Other condition
TS1: consumables, disposables and implants	7%, 7%, 4%, 3%, 3%	10% CAGR	Approval from a stringent regulatory authority country (USA, EU, Canada, Japan, Australia, Switzerland and UK) and sales there; Rs 50 crore minimum investment below Rs 150 crore turnover
TS2: critical components	7%, 7%, 7%, 5%, 3% even without committed value chain integration; 10%, 10%, 10%, 8%, 6% once it is met	2%, 3%, 4% and 5% in years 2 to 5 over year 1 sales	No minimum investment; another 3% for the whole period once committed value chain integration is met; a sales growth shortfall in one year can be made up the next
TS3: high-end devices at a nascent stage	7%, 7%, 7%, 5%, 3% even without committed value chain integration; 10%, 10%, 10%, 8%, 6% once it is met	None	Committed value chain integration mandatory; Rs 50 crore minimum investment below Rs 150 crore turnover
TS4: high-end devices only assembled in India	7%, 7%, 7%, 5%, 4%	None	No greenfield plant needed; committed value chain integration (bill of materials basis) by the end of year 5, and no incentive until it is met

The guidelines (PDF, 1.6 MB)

Source: Department of Pharmaceuticals's own copy.

Checked against the official copy on November 12, 2026.

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