PHARMA

PLI scheme guidelines evoke mix reviews from industry

Some laud the measures taken by the government while others list aspects that should have been considered under the scheme's guidelines

By **Usha Sharma** Last updated **Jul 27, 2020**

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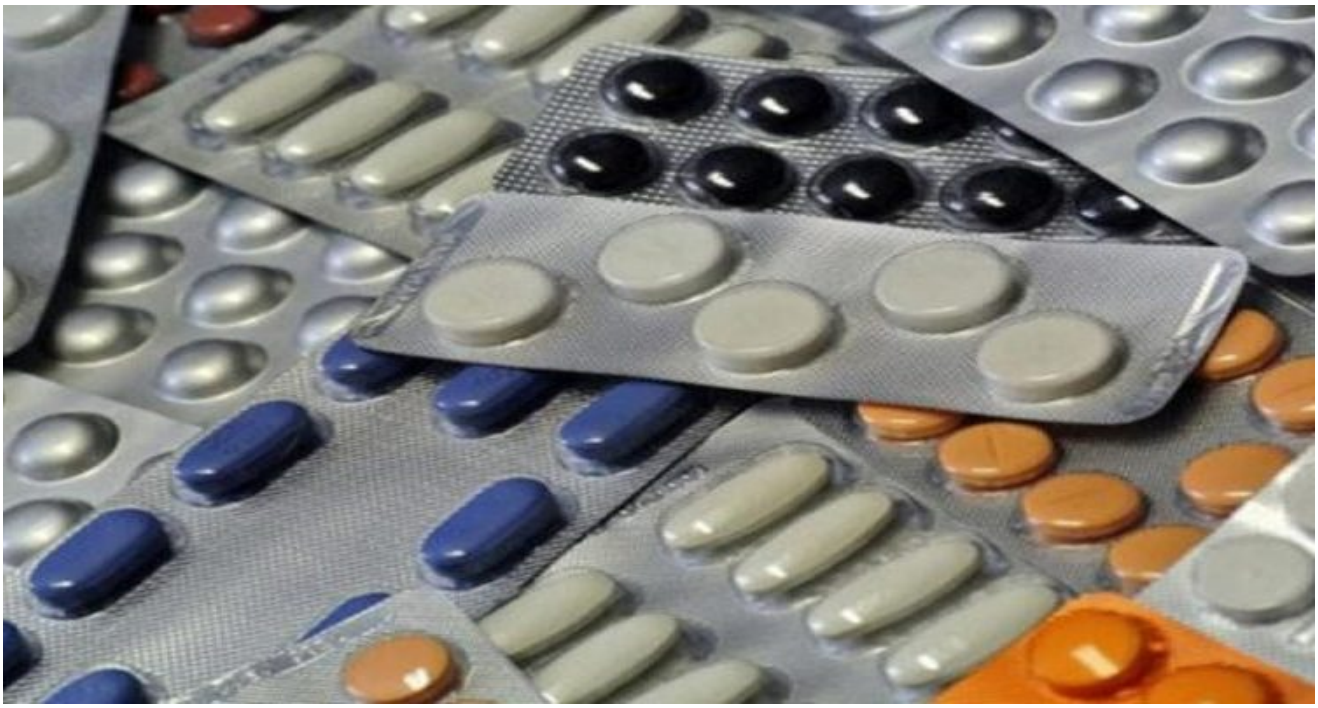

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The Central Government has launched the detailed guidelines for production linked incentive PLI (scheme) and bulk drug parks scheme. The guidelines for the PLI scheme have evoked a mixed reaction from industry stakeholders.

Industry observers pointed out that the evaluation selection criteria of the PLI scheme along with a compulsion of minimum Rs 20 crore investment looks more favourable to big pharma companies and its benefits will remain unchanged for the MSME sector.

According to a senior officer from the DoP, the PLI scheme is not targeted only towards MSMEs. However, he pointed out the benefits for MSMEs and said, “We need size and scale to be competitive viz a viz competing countries. MSMEs will be benefitted immensely from the bulk drug parks scheme. The common facilities at reasonable user charges, land lease rate, electricity, and water will be provided at very competitive rates. All kinds of incentives from state governments, like plug-in facilities, single window system will be really helpful for MSMEs.”

Sudarshan Jain, Secretary-General, Indian Pharmaceutical Alliance (IPA) said, **“**We welcome the government announced detailed guidelines of PLI scheme, although we are studying the scheme criteria, we look forward as it is a promising Scheme. It will help to create self-reliance in the API in over a period of time. At the same time, it will take care of healthcare security of India.”

BR Sikri, Chairman, FOPE, and Vice President, BDMA stated, “A very balanced and transparent guidelines have been issued by the Government of India. It is well known that bulk drugs/APIs are the basics for the growth of the pharma industry. The government has kept in mind the future growth of the pharma sector while announcing the guidelines. The government intends to ensure that there is an uninterrupted supply of quality drugs and their focus is on research also. Atma Nirbharta, the PM’s dream is going to be successful by the introduction of such scheme and incentives.”

The criteria of evaluation for selection of states for bulk drug park shows the commitment of the Government of India. There cannot be any favouritism by the Government to any specific state because the factors kept in mind are very transparent. Each and every point with regards to all parameters such as utility charges, total land availability, uninterrupted availability of water and power, location of the park, connectivity of the park and other incentives including ease of doing business etc. are evidence of the Government of India’s intention. I hope entrepreneurs will come forward soon with their product range to apply for the Central Government’s announced schemes. And state governments will also come forward with their incentive schemes. There is going to be open competition among investors as well as among state governments.”

Mahesh Doshi, President, IDMA, opined, “Overall, it is a good and ambitious plan, which aims to reduce our dependency on import of APIs. Although, it is mainly for the greenfield projects the government has also given consideration to brownfield projects

which have the capacity to build new block/units with fresh investments. They will also be eligible to avail the scheme benefits. However, we are studying the detailed guidelines in detail.

Yogin Mazumdar, Chairman of Bulk Drug Committee, IDMA, articulated, “It is a good initiative of the Government. But the guidelines of the PLI scheme are a bit complicated for MSMEs to easily understand. Unfortunately, it is being restricted to only ‘greenfield’ units. Hence the actual benefit will take more than one year, the time needed to set up fresh facilities, new or even in existing plants. The free capacities of nearly 30 per cent with many existing units will not be utilised under the scheme. Hope the government is separately looking a scheme for utilising the spare capacities available with the ‘brownfield’ units, which would give immediate results towards reducing our dependence over the Chinese.

Further, I have personal experience of the Chinese suddenly reducing export prices if they find capacity being created in India. Now that there is a stipulation for a minimum investment to take benefit under the scheme, investors will look at business security. With this in view, a suggestion was made to include in the guidelines some assurance that in such an event, the Government will take appropriate measures to neutralise the price difference. Unfortunately, we find that there is no mention of such a proactive measure. This would have given some degree of confidence for the continuation of business in spite of any predatory moves by Chinese exporters.

Nipun Jain, Chairman, Small and Medium Pharma Manufacturers Association, expressed, “With minimum investment criteria of Rs 20 crore, the government has diluted the objective of the scheme. Although it is going to create good employment opportunities and reduce our dependence on Chinese imports, it would have been better if the empowering committee would have given consideration to those existing units which have the capacity as well as capabilities to start manufacturing with lesser investment. However, keen pharma MSME entities can look forward towards State government’s proposals for bulk drug parks, which might help them to a certain extent.

Sudhir Vaid, Owner, Concord Biotech informed, “Due to complex nature of the fermentation technologies and highly cost-intensive infrastructure it is very difficult to get the Indian pharma companies to invest in these, high volume and low-value products. India desperately needs the big Indian Indian pharma companies to come

forward and invest in these fermentation-based products, as at present India is totally dependent on China. Concord is planning to invest in the manufacturing of Lincomycin which is an intermediate for Clindamycin."

Vivek Padgaonkar, Independent Healthcare Consultant Ex-Director OPPI, Ex GSK voiced, "The government's move to promote domestic manufacturing of the bulk drugs is a major step in the creation of a self-sufficient healthcare ecosystem in the country. We applaud the efforts of the Department of Pharmaceuticals (DoP) for the greater focus and thrust on the development of the pharma sector in the country.

He added, "We appreciate the uniform, structured and sequenced approach in providing the "Guidelines for the Production Linked Incentive (PLI) Scheme – APIs, KSM and Medical Devices. Future growth of the pharma sector is contingent upon our ability to ensure uninterrupted supply of quality bulk drugs and also our capacity to upscale their manufacturing to meet emergency situations. The government has done the intervention at the right opportune time so that India continues to be the pharmacy of the world in a true sense. The effective implementation of this scheme will help our country to attain self-reliance and reduce import dependence in critical APIs /KSMs/DIs."

However, he also shared some suggestions such as

1. **Application window**: 120 days and approval thereafter within 90 days is too large, it should be shortened to 60 days and 30 days respectively
2. **DPR submissions**: within 180 days of in-principle approval, should be shortened to 60 days
3. **Single window clearance:** Create a single-window clearance system for establishing an API manufacturing unit in India, for example; Telangana state has implemented a single-window clearance system for industrial projects – Telangana State Industrial Project Approval and Self-Certification System (TS-iPASS) for speedy processing of applications and providing various clearances at a single point based on the self-certificate provided by the industry. Single window clearance system is also required for all licences related to testing, imports, development etc.
4. On average, intermediate plants require 9-12 months for approval from the Central Pollution Control Board. For companies with Zero Liquid Discharge, priority approvals are not provided and production quantity restrictions exist. The total time for getting permission for land acquisition to environmental clearances

to commercial manufacturing takes around three to four years (inputs from industry). Therefore, measures such as the following are needed:

- Green clearances should be given within 0-3 months to bulk drug manufacturing units with respect to pollution and effluent discharge from state and central government.
- Categorise bulk drug manufacturing units in the B2 category for environmental clearances – for faster clearances without the requirement for environmental impact assessment (EIA) report
- Allow existing bulk drug companies to modify their product mix or raw materials used without requirement of a new environmental clearance provided their pollution load remains constant (all states need to implement)
- Environmental permission can be provided for capacity addition – based on self-certification for compliance with pollution load requirement.

Thus, stakeholders express different sentiments and opinions about the guidelines. The real outcome of the said schemes will be seen in another two to three years, meanwhile, both the industry as well as the government needs to find a solution which will reduce immediate dependency for APIs from other countries. Therefore, there is a need to design short term strategies as well to make the pharma industry in India self-reliant in producing the required APIs.

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