News

PLI scheme to turbocharge bulk drug industry

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The Government of India's Rs 25000 crore consolidated production linked incentive (PLI) scheme for promoting bulk drugs including the newly approved Rs 15, 000 crore PLI scheme for boosting existing brownfield API units in the country, has won plaudits from experts.

The scheme will become successful led by growth factors like lower cost of manpower, compliance to global norms, evolving trend in technology and innovation to beat competition from China, they opine.

At the same time, the pharmaceutical industry is awaiting further clarification on the second category of active pharmaceutical ingredients (APIs)/key starting materials (KSMs) and drug intermediaries (DIs) under the new Rs. 15,000 crore PLI scheme.

The new PLI scheme is envisaged to boost three categories of pharma products under which category 2 includes APIs, KSMs and DIs.

Besides the clarification sought, industry is also awaiting guidelines on the new Rs. 15, 000 crore PLI scheme. It is also looking towards fulfilling industry's long pending demand for having single window approval mechanism for faster environmental clearance and compliance.

According to officials, the last date of submission of applications for the existing PLI scheme of Rs 10,000 crore announced in July this year is November 30, 2020.

The Indian pharmaceutical industry ranks amongst the top API markets in the world with China being its major competitor. It caters to domestic consumption as well as the export markets to over 200 countries.

As per industry leaders, the new PLI scheme will boost the existing brownfield API units in country and will bring first priority 20 molecules to be produced with scale thus beating Chinese imports.

Industry experts have appreciated the second part of PLI scheme with the cabinet's approval of Rs. 15,000 crore for incentivizing the pharma sector amongst 10 key sectors of the country. In an earlier move, the government had approved Rs. 6,940 crores for 53 bulk drugs and Rs 3000 for the development of bulk drugs park towards making the industry self-reliant and discouraging sub-standard API imports.

According to an industry expert, "This is a welcome change as 35 to 40 per cent of existing brownfield API unit's capacity need to be utilized. It has been learnt that around 20 molecules can be manufactured by synthetic chemistry within a period of two to three months. This can be done considering the fact that the earlier PLI scheme of Rs. 6,940 crore announced in the month of July, 2020 will take minimum two years to fructify. Fermentation based units alone will take three to four years as setting up of greenfield units generally entail a time period of two years time.

The Union Cabinet gave approval to introduce the PLI scheme in10 key sectors for enhancing India's manufacturing capabilities and enhancing exports – Atmanirbhar Bharat.

The three categories which have been identified and included in the PLI scheme for pharma will boost biopharmaceuticals, complex generic drug, patented drugs or drugs nearing patent expiry, cell-based or gene therapy products, orphan drugs, special empty capsules, complex excipients, APIs/KSMs and DIs, repurposed drugs, auto-immune drugs, anti-cancer drugs, antidiabetic drugs, anti- infective drugs, cardiovascular drugs, psychotropic drugs, anti-retroviral drugs, in-vitro diagnostic devices (IVDs) and phytopharmaceuticals.

The Indian pharmaceutical industry is the third largest in the world by volume and 14th largest in terms of value. It contributes 3.5 per cent of the total drugs and medicines exported globally. India possesses the complete ecosystem for development and manufacturing of pharmaceuticals and a robust ecosystem of allied industries. The PLI scheme will incentivize the global and domestic players to engage in high value production.

"API manufacturers of India are trying to strengthen their global footprint by different means mainly by focusing on the improvement of production of complex products by process modification and increasing strategies to increase sales in international market. Indian companies are compliant with many international regulations. Also, improvements in the field of technol

ogy in the country have enabled many manufacturers to venture into highly regulated markets of countries like United States and Europe. This has led Indian API to get the approvals in various countries, increase therapeutic applications and manufacturing facilities and henceforth aggressively strengthening their credibility in regulated markets," according to the Ahmedabad based pharmaceutical consultant, Dr Sanjay Agrawal.

Demand fuels innovation
The demand for micronized APIs, drugs delivered using specialized delivery systems and polymers as well as painkillers formulated have fuelled innovation and specialization in the sector. The most important trend today we see in the global API market is increase focusing on complex formulations in generics as a part of development, Dr Agrawal added.

The Department of Pharmaceuticals (DoP) has recently notified the Rs. 3,000 crore bulk drug parks' promotion scheme and Rs. 6,940 crore PLI scheme for promotion of domestic manufacturing of critical KSMs/ DIs and APIs in India. The gazette notification dated July 21, 2020 superseded the earlier notification of DoP issued on this subject on June 2, 2020.

Talking about bulk drugs incentive scheme of the government, DV Sadananda Gowda, Union minister for chemicals and fertilizers said, "Bulk drugs scheme is to give recognition to Indian pharma industry as Atmanirbhar Bharat. It is also a welcome development that medical devices industry which has 86 per cent dependence on imports clocked in Rs 49,500 crore worth of imports in 2019-20.

According to pharmaceutical expert Anshu Yadav, important players are driving the market growth through their cost effectiveness and regulatory or quality issues and have emerged as manufacturing hubs for the APIs. But in the near future with the government support, improving IP systems and manufacturing standards in India it is expected that India will grow steadily in the coming years. In the near future, India may beat China in the global API market.

“Indian API companies, are continuing to outpace Chinese, Italian and other competitors in terms of DMFs, which are seen as a gradient of quality. Higher quality of the ingredient, coupled with cost-effectiveness has made India increasingly attractive for API outsourcing in the recent times. In fact, India has been recognized as one of the leading global players with the filing of large number of DMFs and dossier registrations for active pharmaceutical ingredients, with several manufacturing facilities approved by the regulatory authorities of developed countries,” Dr Agrawal explained.

Demand for higher quality and lower cost ingredients combined with a growing demand for complex molecules and the generics throughout the supply chain is completely reforming the API industry.

Amitabh Kant, CEO, NITI Aayog, said, “Bulk drug scheme will make India world champion in pharma as manufacturers from around the world are invited to invest which will finally lead to creating a robust ecosystem for pharma and medical devices.”

While giving industry perspective, Ashok Kumar Madan, executive director, Indian Drug Manufacturers Association (IDMA), said, “Industry has been waiting for these detailed guidelines. It’s for first time that that an impetus of Rs. 10,000 crore is being given to augment API production in the country.”

The current status
The Indian market of APIs is taking a new turn and is expected to top nearly US$ 6 billion by the end of 2020. Mainly the Indian APIs market manufacturing segment is dependent on two sectors namely branded and generic or unbranded. Until recently the API market was dominated by the US followed by China which is now considered as a leading producer of API.

China is considered to be the largest producer of API accounting for almost 50 per cent of the global market surpassing the North American market and the United States markets. India is the second largest supplier of generic APIs to the US market with around 30 per cent share.

At present, there are less than 2000 API manufacturing companies in India and China. The leading API suppliers in India are (GSK) GlaxoSmithKline, Aurobindo Pharma, Teva Active Pharmaceutical Ingredients (TAPI), Dr. Reddy’s Laboratories, Pfizer and so on.

Boost to domestic manufacturing
Limiting the Import content for production of listed 41 APIs/KSMs up to 30 per cent is to encourage local manufacture with value- addition for the production Linked Incentive. Given the right implementation, India can aspire to be self reliant in APIs/KSMs in 8-10 years time.

Industry wish list is to also have the government support to utilise the idle capacities of the medium API units with a blanket permission from environment approvals subject to their complying with the overall pollution loads. This will help production of listed APIs in shortest possible time and also prevent these units becoming NPAs.

The PLI scheme
PLI scheme which is applicable only for greenfield projects intends to boost domestic manufacturing of identified KSMs, DIs and APIs by attracting large investments in the sector and thereby reducing India’s import dependence in critical APIs. Under the scheme, financial incentives shall be given for six years based on sales made by selected manufacturers for 41 products which cover all the identified 53 APIs. The tenure of the scheme is from FY 2020-21 to FY 2029-30.

In a bid to ensure effective participation of the industry, the DoP has introduced revised PLI scheme guidelines for promoting domestic manufacturing of KSMs, DIs, APIs and medical devices, removing minimum investment criteria and incorporating export and sale-based production criteria following an appeal by drug and medical device industries.

As per the revised guidelines of PLI scheme for boosting indigenous production of 41 products which cover all the identified 53 APIs for which India is critically dependent on China, the criteria of ‘minimum threshold’ investment have been replaced by ‘committed investment’ by the selected applicant. The change has been made to encourage efficient use of productive capital as the amount of investment required to achieve a particular level of production depends upon choice of technology and it also varies from product to product. The provision for verification of the actual investment made by the selected applicant for the purpose of giving incentives under the scheme continues.

The provision which restricts the sales of eligible products to domestic sales only for the purpose of eligibility of receiving incentives has been deleted, bringing the scheme in line with other PLI schemes and encouraging market diversification.

A change has been made in the minimum annual production capacity for 10 products viz tetracycline, neomycin, para amino phenol (PAP), meropenem, artesunate, losartan, telmisartan, acyclovir, ciprofloxacin and aspirin. Minimum annual production capacity is a part of eligibility criteria under the scheme.

The last date for receiving applications under the scheme is now extended by a week to November 30, 2020.

The guidelines of the scheme were originally issued on July 27, 2020 which has now been superseded by revised guidelines issued by the DoP on October 29, 2020.

The revised guidelines were approved by NITI Aayog chairman led empowered committee of the scheme following recommendation of technical committee set up under the scheme which received suggestions from the DoP. Industry associations such as IDMA, BDMA, SMPMA etc have made representations to the department seeking removal of threshold investment criteria and inclusion of export and sale-based production criteria in the PLI scheme to encourage participation of more manufacturers.

Welcoming the revised guidelines of the PLI scheme, Yogin Majmudar, chairman of Bulk Drug Committee, IDMA said, “The removal of minimum investment criteria is a welcome step. The threshold investment requirement was a constraint for the manufacturers who can make minimum investment to produce identified products considering they already have common surplus utilities available to them.”

As per PLI scheme guidelines dated July 27, 2020, threshold investment was Rs. 400 crore for four fermentation-based products and Rs. 50 crore for ten fermentation-based products. Similarly, threshold investment was Rs. 50 crore for four chemically synthesised products, and Rs. 20 crore for 23 chemically synthesised products.

Majmudar also hailed inclusion of export criteria in the revised PLI scheme, saying that this will increase the number of the applicants in the scheme.

If there are more than four applicants for 27 chemical synthesised products and more than two applicants for 14 fermentation-based products, selection of applicants for the incentive will be done on the basis of marks obtained by them in the evaluation criteria which include committed annual production capacity and quoted sale price etc.

It is learned that so far DoP has received around 125 applications for manufacturing of bulk drugs under the PLI scheme.

The pharmaceutical Industry is still in the wait-and-watch mode on making investment in manufacturing identified bulk drugs as there are chances of a steep decline in prices of Chinese APIs, once Indian manufacturers commence production of these bulk drugs, said an industry expert.

It will take around two years to commence operation of greenfield projects of identified KSMs, DIs, APIs. China could reduce prices of these products to discourage their local production by then, he said.

In the past, there were instances of Chinese API makers reducing prices of raw materials to sabotage the local manufacturing of bulk drugs. The government had also not come forward to support the manufacturers of fermentation-based products grappling with dumping of low-priced Chinese

products, he added.

With the minimum investment criteria has been done away with, the provision of committed investment mentioning that using ancillary facilities of existing plants will not qualify for committed investment to be made under the scheme is a little bit confusing to manufacturers. The provision should have been removed, said another industry expert.

Hailing the revised PLI scheme guidelines, Nipun Jain, chairman of Small and Medium Pharma Manufacturers Association said replacement of the criteria of threshold investment with committed investment is a great relief. It will encourage MSME manufacturers to participate in the PLI scheme in large numbers. This will make the country self-reliant in the production of APIs in the long run. Currently, India is known as the pharmacy of the world. Besides this, it supplies APIs across the world whenever needed. The revised guidelines will make it a worldwide leader in APIs."

Similarly, there is replacement of the criteria of 'minimum threshold' investment with 'committed investment' by the selected applicant in the revised PLI scheme guidelines of medical devices.

Besides this, the eligibility criteria of minimum sales threshold has been amended in line with projected demand, technology trend and market development, for the purpose of availing incentive under the scheme.

The tenure of the scheme has been extended by one year considering the capital expense expected to be borne by the selected applicants in FY 2021-22. Accordingly, the sales for the purpose of availing incentives will be accounted for five years starting from FY 2022-2023 instead of FY 2021-2022.

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