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A SELF-RELIANT PHARMA INDUSTRY

Relevant for: Science & Technology | Topic: Biotechnology, Genetics & Health related developments

The pharmaceuticals industry is a key sector for the Atmanirbhar Bharat programme. The objective of the Phase-I Production-Linked Incentive (PLI) scheme in this sector was to reduce import dependence on active pharmaceutical ingredients (APIs), drug intermediates (DIs) and key starting materials (KSMs). This scheme was expected to attract a lot of interest as countries had begun to adopt measures to reduce their dependence on China for APIs. However, the response to this scheme did not meet expectations.

A total of 239 applications were received in two rounds from an industry of over 3,000 firms. Of these, 61 were selected. As 11 beneficiaries withdrew from the scheme, the number reduced to 50 as on December 9, 2021, against the maximum number of 136 beneficiaries as mentioned in the guidelines. No beneficiary was identified in five of the 41 products notified for the scheme.

A recent study conducted by us on this scheme, published as a working paper of the Institute for Studies in Industrial Development (ISID), shows that India needs a strategy, not just a scheme, to realise the objective of reducing import dependence. There are three areas where this PLI scheme requires modifications. Other complementary measures also need to be put in place for India to become self-reliant in APIs, DIs and KSMs.

Firms will invest in production in India if they see a prospect of producing at prices cheaper than the cost of imports. As cheaper imports from China are critical for maintaining their global competence in the export of formulations, investors will face an investment uncertainty if the proposed measures do not ensure the price competitiveness of domestic production. More than half the turnover of this industry is from exports. Imports from China are reported to be cheaper by 35–40% compared to indigenously produced products. So, any strategy aimed at achieving self-reliance should focus on achieving price competency in production.

Technology plays a very crucial role in reducing import dependence as Indian producers have constraints in overcoming some of the advantages of Chinese producers such as scale of operations. Without appropriate technology, APIs/DIs/KSMs manufacturers in India will not be in a position to beat their Chinese counterparts in pricing. This PLI scheme doesn't have a technology component.

Two, this scheme also insists on new manufacturing facilities, which doesn’t make business sense for firms which have idle capacities. Many firms used to produce these products and have wound up production as cheaper imports began to flow from China. Permission to utilise existing but inoperational or underutilised facilities for production would have elicited a better response.

Three, the history of development of the indigenous pharmaceutical industry in India shows the significance of an industrial policy that is in tandem with trade and science and technology policies. This PLI scheme remains a standalone measure; it is not connected to other relevant policy measures.

Nearly three-fourth of the production of pharmaceuticals in India is by MSMEs. Historically, large private sector firms have been interested in formulations, not APIs. As APIs are sold with their chemical names and without branding, large firms have no interest in their production. The production of APIs by large firms, if at all, is largely for captive consumption. The focus of the PLI Phase-I scheme, however, is on large firms. The data we obtained for 13 of the beneficiary firms shows that all of them are large firms, if the definition of MSMEs that existed at the time of

announcement of the scheme is used. If the new definition is used, all except one are large firms. It seems like policymakers are interested in taking advantage of efficiencies associated with the scale of operations by encouraging large firms. But it is equally important to include smaller firms which are into the KSMs/DIs/APIs business in a major way.

In spite of the two rounds of applications, no beneficiary was identified (or no application was received) in five products, which are all antibiotics. It appears from our interactions with the industry that four of the five products — Neomycin, Gentamicin, Tetracycline and Clindamycin base are APIs that are not used much by the industry. This may be one of the reasons for the lack of enthusiasm by the industry. However, we should note that such APIs may be of great significance for public health. In such cases, public sector enterprises (PSEs) should be tasked with the production of APIs and their KSMs and DIs. The lead role that PSEs had played in the development of an indigenous pharmaceutical industry in India can never be forgotten.

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There are good economic and strategic reasons for an FTA that will spell many opportunities for both countries

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