A Hard Pill to Swallow

Despite the government’s efforts to boost domestic manufacturing of various drugs, raw materials and medical devices, their imports have only increased. On top of that, uptake of the PLI scheme is moving at a slower-than-expected pace. By Neetu Chandra Sharma
RISING DEPENDENCE

India's imports of raw materials required in manufacturing drugs have increased consistently over the past few years.

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<tr>
<th>Year</th>
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**BOX DRUG IMPORTS - A GRAPHS|

**BIOLOGICALS - HAMMER MEDICAL PRODUCTS

Source: CME Economic Outlook

India’s imports of raw materials required in manufacturing drugs have increased consistently over the past few years. The government has introduced several schemes, including PLI to boost domestic manufacturing. "As a step towards Astha Nirbharta (self-reliance), the government is focusing on production of high-value pharmaceuticals and high-end medical devices," Union Health Minister Mansukh Mandaviya told Business Today.

While the PLI scheme for manufacturing drugs and APIs has managed to draw good investments, schemes aimed at promoting production of high-end medical devices and bulk drugs have received lukewarm response. "The current PLI scheme has an outlay of around $1 billion. While promising, there has been a slow pace of response to the scheme, with only a few companies coming up," said a top industry executive.

It is important to drive investments from the middle market, says Suresh Subramanian, National Life Sciences Leader, EY India.

Let us take a closer look.

**PLI FOR DRUG MANUFACTURING AND APIs

In March 2020, India launched the PLI scheme to promote domestic manufacturing of critical key starting materials (KSMs), raw material to make APIs), drug intermediates and APIs in the country. "The PLI scheme aims to reduce India's import dependence on other countries through indigenous production, by attracting large investments in the sector ensuring their sustainable domestic supply," says Mandaviya.

So far, the scheme has attracted investments of $15,450 crore from 27 selected companies, including 10 KSMs, against a target of $17,450 crore. Under this scheme, the government has identified 22 raw materials for which to invest about $100 million each. For instance, products based on fermentation (to produce citric acid, enzymes and therapeutic proteins, etc.) and hybrid technology (to produce generic drugs, small molecule drugs and vaccine) will get incentives amounting to 25 per cent of fixed capital cost (FCC) and 25 per cent of FCC and 25 per cent of FC for FY23. Products based on chemical synthesis (these are antibacterial compounds such as antibiotics, sulfa drugs and injectable, sildenafil, sertaconazole, and non-steroidal anti-inflammatory drugs, etc.) will get incentives amounting to 15 per cent of FCC and 15 per cent of FCC for FY23. Products based on chemical synthesis (these are antibacterial compounds such as antibiotics, sulfa drugs and injectable, sildenafil, sertaconazole, and non-steroidal anti-inflammatory drugs, etc.) will get incentives amounting to 15 per cent of FCC and 15 per cent of FCC for FY23.

**SPANNERS IN THE WORKS

It takes three to four years to set up an API plant in India, compared to 1-2 years in China. The cost advantage of importing APIs from China is likely to reduce in magnitude over time. Depending on the capacity, a new plant can cost up to $3-10 million to set up. With 1,500 contract research and manufacturing services, competition is fierce in the undifferentiated market. There are a limited number of skilled and trained workers in the industry.

Per the government's roadmap, the PLI scheme has been designed to ensure that India becomes self-reliant in the production of critical raw materials required in manufacturing drugs and medical devices. The world relies on India's pharma industry—the world's third-largest drug producer by volume—for its medicinal needs. With nearly 6 per cent of India's total imports of medical products worth $15.34 billion, India's PLI scheme has made inroads in pharmaceuticals and medical devices manufacturing.
API facility in Canada and a new facility in India is expected to increase the capacity of its US FDA-approved API facility in Vapi, Gujarat, with plans to produce a new range of APIs.

**PLI SCHEME FOR BULK DRUG PARKS**

This provides for financial assistance to create common infrastructure facilities at bulk drug parks. However, it has not evoked a lot of interest. So far, only three states—Tamil Nadu, Himachal Pradesh and Gujarat—have received approvals to set up such parks.

And against a target investment of Rs 2,000 crore, this segment has attracted investments of only Rs 2,000 crore. “India has lost the advantage of bulk drug manufacturing over the years. China has built its presence because of the support received in multiple areas, from plant prices, interest rates and price subsidies, among others. Regaining the advantage and achieving self-sufficiency will be a long process,” explains Sudhanshu Jain, Secretary General of the Indian Pharmaceutical Alliance.

The cost of production in India is 50 per cent less than in developed nations, but this is still around 20 per cent higher than China. This is attributable to raw materials being 30-30 per cent costlier, electricity being 20 per cent more expensive, and other costs such as financing, logistics, transportation, etc. being 30-40 per cent more expensive,” says Arundhati Guha, Executive VP of Healthcare and Life Sciences at a chemical, tech-enabled consulting, research and advisory firm.

Pharmaceutical companies believe that the scheme is restrictive in nature and offer a lot of support to innovation, which would not make it worth participating. Arush Jain, Director of Akura Drugs & Pharmaceuticals, says the scheme is restrictive only for the domestic market but not for exports. “In India, R&D incentives account for 2.5 per cent of total tax incentives, but the pharma R&D incentives stand at just 2-3 per cent. The current PLI scheme can be expanded to link it to research for efficient production and sustainability of the domestic and export markets,” she says.

Glen Saldanya, Chairman & MD of Glenmark Pharmaceuticals, has a solution. “The PLI scheme should be linked to research and innovation. India is a powerhouse in the pharma industry today. There are many areas where we build a lot of capabilities. One is pure innovation, particularly on the biologics side,” he says. Arun Mahanta, MD & CEO of Vaccine & Biologicals Limited (VBL) “Any support for the generics business, moving up the value chain, fermentation-based APIs, high potency intermediates and biotechnology-based APIs, is welcome. We already are among the highest R&D spenders at 16 per cent.”

**PLI FOR MEDICAL DEVICES**

Launched in March 2022, this segment of the scheme aims to establish domestic capabilities in manufacturing high-end medical devices, especially those that are being imported. The success of this segment is also very limited, as there are not many manufacturers in the high-end end devices around the world. “So, it’s understandable that hardly 10-20 per cent of these will see taking the risk to make in India, especially with a lack of incentives, protective tariffs and an unpredictable regulatory implementation framework,” says Rajiv Nanth, MD of Hindustan Syringes & Medical Devices.

Amidst a parliamentary panel on health, the government has urged the government to consider expanding the scope of the PLI scheme to other high-value dependent medical devices and incentivize manufacturing of critical raw materials and components. While some of these medical technologies require big-ticket capex, there are others that are niche products that do not demand very high capex. We have been requesting the government to widen the scope of the scheme to encourage investment by domestic champions,” says Nath, also the Forum Coordinator at the Association of Indian Medical Device Industry.

Against a committed investment of Rs 1,053 crore over a period of five years, an investment of Rs 1,053 crore has been reported. Experts consider the 3 per cent incentive on incremental rupee sales as very low. For instance, if a company sells 150 products equal to its investment value or thrice the investment, then Rs 1,000-crore investment will add to sales of Rs 1,000-3,000 crore. A 3 per cent incentive on this will be Rs 30-90 crore per year. “That’s very low utilisation. So, unless the government corrects the tariff structure as it did for consumer electronics and mobile phones, people will not step forward to invest,” says Nath.

**THE WAY FORWARD**

Potential investors also need the assurance of a market to be able to produce and sell the goods, and earn expected profits. “If the prospects of successfully competing against Chinese products are poor, then the attraction of the facilities at the bulk drug parks may not be enough to induce investments,” says a report by New Delhi-based think tank Research and Information System for Developing Countries (RIS).

“India is a powerhouse in the pharma industry today... There are many areas where we build a lot of capabilities. The one missing piece is pure innovation on the biologics side”

Glen Saldanya
Chairman & MD, Glenmark Pharmaceuticals

“PLI scheme [for pharma] aims to reduce India’s import dependence on other countries, through indigenous production, by attracting large investments”

Mansukh Mandaviya
Union Minister of Health and Family Welfare: Minister of Chemicals and Fertilizers

“Again, the fact that incentives are paid as a percentage of sales is also acting as a deterrent, the report adds. If the schemes announced by the government enable Indian firms to produce and sell more, then imports from China will indeed go down, says Saurabh Chauhan, author of the report and former professor of economics at the Indian Institute of Management Kolkata. But depending on the prices charged by Chinese companies, Indian firms may not be able to compete as now.

“The government needs to sort these issues out if we need to make India self-reliant in pharma in the real sense,” says Vinayak Shah, National President of Indian Drug Manufacturers Association, who is also the Director of Isha Laboratories, a pharma company. “However, making India self-reliant in pharma is not a sprint, it is a marathon. We cannot be looking at short-term self-reliance on supply chains...”

That marathon has begun in earnest. While the start may not have been as brisk as anticipated, the possibility of things accelerating, with the right levers being moved, is not to be dismissed.