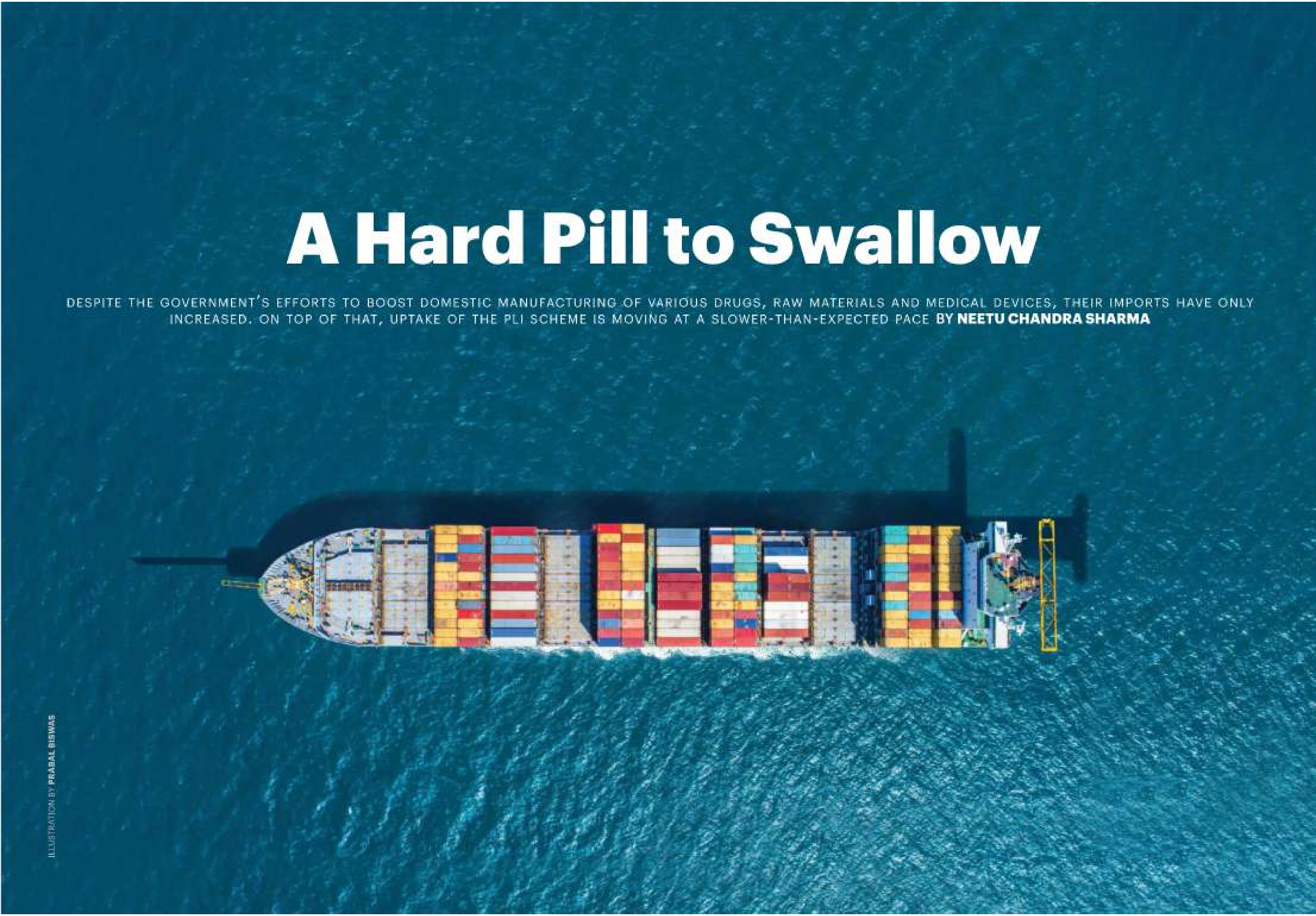

A Hard Pill to Swallow

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**

ILLUSTRATION BY **PRABAL BISWAS**

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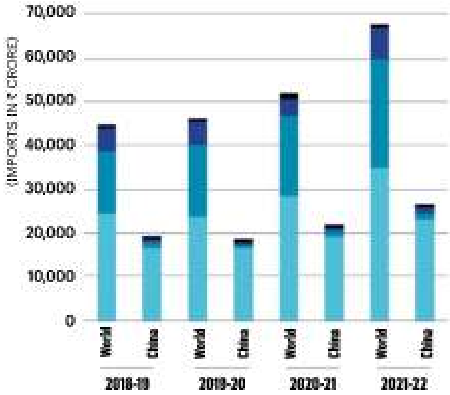
SWELLING RESEARCH COSTS and import dependency—two major afflictions that India's pharmaceuticals industry seemed helpless against until a few years ago. Hopes were raised when the central government unveiled a production-linked incentive (PLI) scheme in the middle of the pandemic to foster domestic production of key import items such as active pharmaceutical ingredients (APIs), the raw material for making a drug. The pandemic had stifled global supply chains and exposed India's heavy dependence on China for its pharma requirements. At a time when basic raw materials for drug-making became scarce because of the lockdowns, India's PLI scheme was aimed at muscling up the domestic $50-billion pharma industry and ring-fencing it from Covid-19-like future black swan events and, in the bargain, reduce its dependence on China.

However, things have not panned out the way they were expected to; at least not yet. Almost three years since the PLI scheme was launched, India's reliance on China for APIs and other pharma products has only increased. Per data from the Ministry of Chemicals and Fertilisers, the import of bulk drugs or APIs and drug intermediates (materials produced during API synthesis) from China rose 20 per cent from FY21 to ₹23,273 crore in FY22, which was 66 per cent of India's total imports of medical products worth ₹35,249 crore that fiscal. And data from the commerce ministry shows that imports of 30 key medical devices have gone up by 25-152 per cent during April-December 2022 compared to a year ago.

The above numbers are emblematic of the slow progress the government's PLI scheme has made in pharma

RISING DEPENDENCE

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



■ BULK DRUGS, DRUG INTERMEDIATES ■ DRUG FORMULATIONS, BIOLOGICALS ■ SURGICALS ■ AYUSH AND HERBAL PRODUCTS

SOURCE CMIE ECONOMIC OUTLOOK

and medical devices manufacturing.

The world relies on India's pharma industry—the world's third-largest by production volume—for its medicinal needs, with nearly 8 per cent of all pharma products by volume being produced in the country. In the past nine years, the Indian pharma industry has grown steadily at a CAGR of 9.43 per cent. And its size could increase to $65 billion by 2024 and $130 billion by 2030, predicts the Department of Pharmaceuticals. Despite such strong numbers, India's import dependence on China remains alarmingly high—as much as 90-100 per cent for some critical raw materials that go into manufacturing high-selling drugs such as paracetamol, penicillin, ibuprofen and vitamin B12, among others.

Another nuance is that Covid-19 has provided India a chance to revamp its pharma industry and switch from primarily producing generics to manufacturing higher-margin licensed drugs. Amid this backdrop, the Indian government had introduced several schemes, including PLI, to boost domestic manufacturing. "In a step towards *AatmaNirbharta* (self-reliance), the government is focussing on production of high-value pharmaceuticals and high-end medical devices," Union Health Minister Mansukh Mandaviya tells *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 drug parks have received lukewarm response. "The current PLI scheme has an outlay of around $1 billion. While promising, there has been a low to moderate response [to the scheme], with only a few companies in the top and bottom tiers participating. 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 1.0 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 ₹16,199 crore from 55 selected applicants, including 20 MSMEs, against a target of ₹17,425 crore. Under this scheme, the government has identified 41 products to provide incentives to for six years. For instance, products based on fermentation (a process for cultivating microorganisms to make antibiotics, insulin, enzymes and therapeutic proteins, etc.) will get incentives amounting to 20 per cent for FY24-27; 15 per cent for FY28; and 5 per cent for FY29. Products based on chemical synthesis (these are antibacterial substances such as organoarsenicals and sulfa drugs, penicillin, streptomycin, tetracycline and erythromycin) will receive 10 per cent as incentive for FY23-28.

To bolster its move, just nine months after the launch of PLI 1.0, the government approved another scheme (PLI 2.0) for the pharma sector with an outlay of ₹15,000 crore. In order to ensure wider applicability, PLI 2.0 divides pharma firms into three distinct categories based on their global manufacturing revenue (GMR) in FY20: Category 1 for those with GMR of above ₹5,000 crore; Category 2, with GMR of ₹500-5,000 crore; and Category 3 with GMR of less than ₹500 crore, with incentives ranging from 5-10 per cent for a period of six years. The scheme includes APIs from FY21 to FY29.

These incentives, industry experts believe, are too little for smaller players to take the plunge, because of the high investments. "The scheme was launched only to leverage the bigger pharma companies to bring investments into India, in the same way they were doing in other countries," says Daara B. Patel, Secretary-General of the Indian Drug Manufacturers' Association (IDMA). Agrees Harish Jain, Senior Vice President of the Federation of Pharma Entrepreneurs and a member of the Pharmaceuticals Export Promotion Council of India: "Over 71 per cent of benefits of the PLI scheme have gone to the top companies, but the MSMEs have barely received the benefits of around 11 per cent," he says.

Pharma majors such as Sun Pharma, Aurobindo Pharma, Dr. Reddy's, Lupin, Mylan Laboratories, Cadila Healthcare, Cipla and Glenmark—all of them with big API businesses—benefitted immensely from the scheme. Over the next five years, Indian API-producing firms are anticipated to grow at a CAGR of 9-11 per cent, according to Sushil Finance Group, a broking house.

The PLI scheme will further help in improving tech capabilities, capacity utilisation and competitiveness, Sun Pharma recently said. *BT*'s emailed questionnaire on PLI to the company remained unanswered at the time of going to press, as did queries emailed to Dr. Reddy's, Aurobindo Pharma, Lupin and Cipla.

Meanwhile, Biocon's subsidiary Syngene International has invested in an API plant in Mangaluru, Karnataka. Piramal Pharma is another firm that is building an

SPANNERS IN THE WORKS

◂ It takes three to four years to set up an API plant in India, compared to 1-1.5 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 players, competition is intense in the undifferentiated market

◂ There are a limited number of skilled and trained workers in the industry

API facility in Canada and Aarti Industries is expanding the capacity of its USFDA-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—Telangana, Himachal Pradesh and Gujarat—have received approvals to set up these parks. And against a target investment of ₹4,138 crore, this segment has attracted investments of only ₹2,019 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 power subsidies, among others. Regaining the advantage and achieving self-reliance will be a long process," explains Sudarshan Jain, Secretary General of Indian Pharmaceutical Alliance.

The cost of production in India is 50 per cent less than in developed nations, but it is still around 18 per cent higher than China. This is attributable to "raw materials being 25-30 per cent costlier, electricity being 20 per cent more expensive, and other costs such as financing, logistics, transportation, etc., being 30 per cent more expensive", says Arindam Gupta, Executive VP of Healthcare and Life Sciences at 1Lattice, a tech-enabled consulting, research and advisory firm.

Pharma companies believe that the scheme is restrictive in nature and does not provide a lot of support to innovation, which would make it worth participating in. Arushi Jain, Director of Akums Drugs & Pharmaceuticals, says the scheme is restrictive not just for the domestic market but also from the point of view of exports. "In India, R&D incentives account for 7.5 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.

Glenn Saldanha, 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 built a lot of capabilities. The one missing piece is the pure innovation, particularly on the biologics side," he says. Agrees Mahima Datla, MD & CEO of Vaccines and Branded Formulations at Biological E: "Any support for the generics business, moving up the value chain, fermentation-based APIs, high potency intermediates and peptide-based APIs, interests us. We already are among the highest R&D spenders at 15-16 per cent."

BOOSTER SHOT

An overview of the incentives available under the PLI scheme for various pharma segments

Financial outlay (₹ crore)	Duration	Focus
15,000	FY21-FY29	To promote manufacturing of pharmaceuticals, including APIs
6,940	FY21-FY30	To promote local production of critical key starting materials, drug intermediates and APIs
3,420	FY21-FY28	Provides 5 per cent incentive on incremental sales of medical devices made in India
3,000	FY21-FY25	Will provide financial assistance to build common infrastructure facilities at three bulk drug parks

HEALTH CHECK

Amount committed for the PLI scheme under various segments

Expected Investment	Reported Investment	Sector	Project status
17,425	16,199	Pharmaceuticals	55 applicants in the first year of implementation
4,138	2,019	Bulk drugs	51 applications approved
1,059	714	Medical devices	14 projects commissioned for 34 products

FIGURES IN ₹ CRORE;
SOURCE MINISTRY OF CHEMICALS AND FERTILISERS

PLI FOR MEDICAL DEVICES

Launched in March 2020, 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 for high-end devices around the world. "So, it's understandable that hardly 10-20 per cent of these will consider taking the risk to make in India, especially with a lack of investments, protective tariffs and an unpredictable regulatory implementation framework," says Rajiv Nath, MD of Hindustan Syringes & Medical Devices.

Amid this, a parliamentary panel on health has urged the government to consider expanding the scope of the PLI scheme to other import-dependent medical devices and incentivise 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 ₹1,059 crore over a period of five years, an investment of ₹714 crore has been reported. Experts consider the 5 per cent incentive on incremental sales as very low. For instance, if a company sells products equal to its investment value or three times the investment, then ₹1,000-crore investment will lead to sales of ₹1,000-3,000 crore. A 5 per cent incentive on this will be ₹50-150 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 even the attraction of the facilities at the bulk drugs plants may not be enough to induce investments in the first place, says a report by New Delhi-based think tank Research and Information System for Developing Countries (RIS).

"The 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 FERTILISERS

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

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CHAIRMAN & MD, GLENMARK PHARMACEUTICALS

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 Sudip Chaudhuri, 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 of now.

"The government needs to sort these [issues] out if we need to make India self-reliant in pharma in the real sense," says Viranchi Shah, National President of Indian Drug Manufacturers Association, who is also the Director of Saga 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 right 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. BT

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