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In India’s pharmaceutical services sector, government and industry visions clash

Modi government pushes for self-sufficiency in manufacturing drugs, but outsourcing companies have other plans

by ***Rick Mullin***

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Credit: Hikal

A technician is at work at Hikal's Bangalore facility. The company is among the drug contract development and manufacturing firms in India competing with US and European suppliers.

India’s prime minister, Narendra Modi, announced an economic development scheme last year called Atmanirbhar Bharat, which translates roughly to “self-reliant India.” Introduced as a response to COVID-19, the program, often called the production-linked incentive (PLI) plan, offers financial support for building or expanding production assets in 10 sectors, including pharmaceuticals.

Despite a reputation for being a major source of pills and active pharmaceutical ingredients (APIs), India actually depends heavily on China to fulfill its pharmaceutical needs. A recent report by the consulting firm PwC estimates that about half the country’s API requirements—including for finished drugs that it subsequently exports—are met by China. And the raw materials and intermediates for the other half come almost entirely from China.

The potential **liabilities of reliance on China**, long a concern in Indian industry and government, became an immediate threat when the pandemic hit and increased demand for drugs needed to treat COVID-19. India for a short time **halted exports** of several products, including the purported

COVID-19 treatment hydroxychloroquine. As the US government **took action** to reshore pharmaceutical production and Europe introduced a **strategy**of support for local producers, India also turned up the heat on manufacturing self-sufficiency.

The $1.8 billion **PLI program for pharmaceuticals** is intended to turn India into a global hub for making bulk drugs and medical devices. Among other things, it offers incentives of up to 30% of sales for investments in 41 starting materials and intermediates required to make 53 antibiotics, analgesics, and other APIs deemed essential. The government says it will also establish three bulk-drug manufacturing parks over the next 5 years.

India's drug industry officially welcomed the PLI program. "The announcement by the government will help revive the API industry in the country and will help the sector regain dominance that was lost over the years," Satish Reddy, president of the Indian Pharmaceutical Alliance, a trade association, says in a statement. Reddy, chairman of the Indian drugmaker Dr. Reddy's Laboratories, called the manufacturing parks a step in the right direction and expressed optimism that India can advance as a global hub for bulk drugs.

The view among managers at India's contract development and manufacturing organizations (CDMOs), which make APIs for other firms, is more nuanced. These executives acknowledge a need for better infrastructure, but they see their firms as having moved beyond the manufacture of the essential, but basic, drugs that the government effort is intended to support.

Roger Laforce, a longtime industry figure who heads CDMO business development efforts at the Indian firm Hikal, notes that the Modi government has taken a nationalistic tack in its business policies The PLI program may be scoring political points, he says, "but it hasn't trickled down to the industrial level."

> "We are delisting all our critical materials and intermediates from China.
>
> — ***Manoj Mehrotra,*** *president of pharmaceutical business, Hikal*

Indeed, executives at several prominent Indian CDMOs say they are not taking advantage of PLI payments because the program is for essential drugs rather than the custom-synthesized, patented drugs their industry is emphasizing. Executives do, however, look forward to the option of operating in technology parks, which offer shared infrastructure and other cost-saving amenities.

With the PLI program, the government hopes to foster self-reliance with incentives to produce drugs and precursor chemicals that have been outsourced primarily to China over the last quarter century.

But such projects are huge undertakings, says Satyanarayana Chava, CEO of the CDMO Laurus Labs, and don't necessarily provide the desired security. "The question of back integration depends on how far you go backward," Chava says. "If you buy intermediates from China, that means you are not self-sufficient."

Laurus, which focuses on custom synthesis for "innovator" drug companies, is not applying for PLI payments, Chava says. Instead, the firm will focus on its ongoing 2-year, $170 million project to expand API manufacturing by 30%.

Changes to the supply chain will take time, Chava cautions. India will continue to be a strong player in the API market, but it will also be supplied by China for the foreseeable future.

Credit: Laurus Labs

A technician adjusts equipment at Laurus Lab's oncology active pharmaceutical ingredient facility in Vizag.

Avra Labs, another CDMO, won't apply for PLI payments either, according to Chief Operating Officer Chandra Ramarao."We are working on drugs that don't fall into the category that the government lists as essential drugs," he says. "We work in oncology and other areas."

Credit: Avra Labs

Avra Labs hosts a customer visit at its manufacturing site in Vizag.

An growing number of Indian companies are in the same situation, Ramarao says. "We have moved up the value chain from making raw materials to purchasing them from China," Ramarao says of the industry. "In the '80s we made a lot of antibiotics and were pretty good at it." Chinese companies followed suit. "What has happened is that we have been buying a lot from China and doing the formulations and making final APIs."

Sai Life Sciences also stresses custom synthesis. Although India has a reputation as a big supplier of essential APIs like antibiotics and analgesics, CEO Krishna Kanumuri argues that the country's drug manufacturing has evolved and diversified over the past 20 years.

"India started to become a global supplier of generics in the late 1990s," Kanumuri says. "In the early 2000s, five or six companies became global suppliers for the innovator space. We started supplying discovery and development services."

The shift occurred as buyers at innovator drug companies recognized Indian firms as alternatives to traditional European and US contractors. "Getting to market early, growing with the customers, and understanding their expectations—there is no silver bullet," Kanumuri says. "You need to earn their trust over time."

Although the Indian industry's emphasis is changing, executives see China's dominance of raw material supply as a problem, and some are taking action.

Manoj Mehrotra, president of Hikal's pharmaceutical business, says his firm is looking to diversify its list of raw material suppliers beyond China. "We are delisting all our critical materials and intermediates from China," he says, "looking for a second source in India and Europe." In some cases, Hikal is updating its processes for starting materials it has ceased manufacturing, contracting the production to suppliers who will use Hikal's technology.

Hikal is also putting about $50 million into expanding the firm's three sites in India, according to Anish Swadi, its president of strategy and business development. "We took a decision to invest in capacity and build up technology capabilities about 18 months ago," he says.

With such buttressing of its production base, India is in a strong position to help Western drugmakers and governments secure API supply, Swadi and Mehrotra say. They and other Indian CDMO executives say US and European companies' effort to diversify API sourcing is largely a matter of finding alternatives to China, which creates an opportunity for India.

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> — ***Satyanarayana Chava,*** *CEO, Laurus Labs*

Mehrotra suggests that vows by Western government to fully reshore API production aren't realistic. "Those are political statements," he says. "On the ground, the ecosystem is not favorable yet either in the US or in Europe to get big-time into APIs," given the dismantling of the manufacturing base over the past 25 years. "We don't see it coming back until the next decade or so."

Although Hikal has not applied for PLI payments, Swadi says the firm would consider setting up operations in one of the new technology parks. Their locations have not been announced, but sources expect a park to open in Visakhapatnam, known as Vizag, in the southeast state of Andhra Pradesh, and another in Haryana, a state in the north.

James Bruno, president of the consulting firm Chemical and Pharmaceutical Solutions, says India needs the technology parks.

"They are using the Chinese model," Bruno says, in which the government invests in infrastructure, allowing producers to share resources at a low cost. "For India, the one thing they need to invest heavily in is environmental management," he says. "And the industrial parks seem to do a really good job of doing that."

It will be some time before the PLI-funded parks are open, however. And Ramarao at Avra says it's hard to say if India will ever make significant headway in back-integration as a bulwark against buying from China. "Is it going to be easy for us to catch up with China?" he asks. "We don't know, because we've focused our attention on higher-value APIs and formulations."

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