A Bitter Pill | Pharmaceuticals

India lost the competitive edge in manufacturing APIs-the building blocks of medicine-to China over the past two decades. Regaining it will be a challenge.

Amarnath K. Menon
July 4, 2020 ISSUE DATE: July 13, 2020 | UPDATED: July 4, 2020 08:45 IST

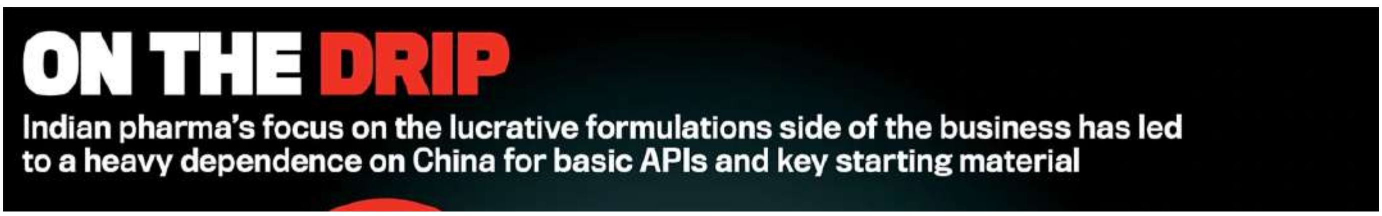
OVER THE COUNTER: Staff dispense medicine at the Govt Women and Children Hospital in Thiruvananthapuram (Photo: M R Manu)

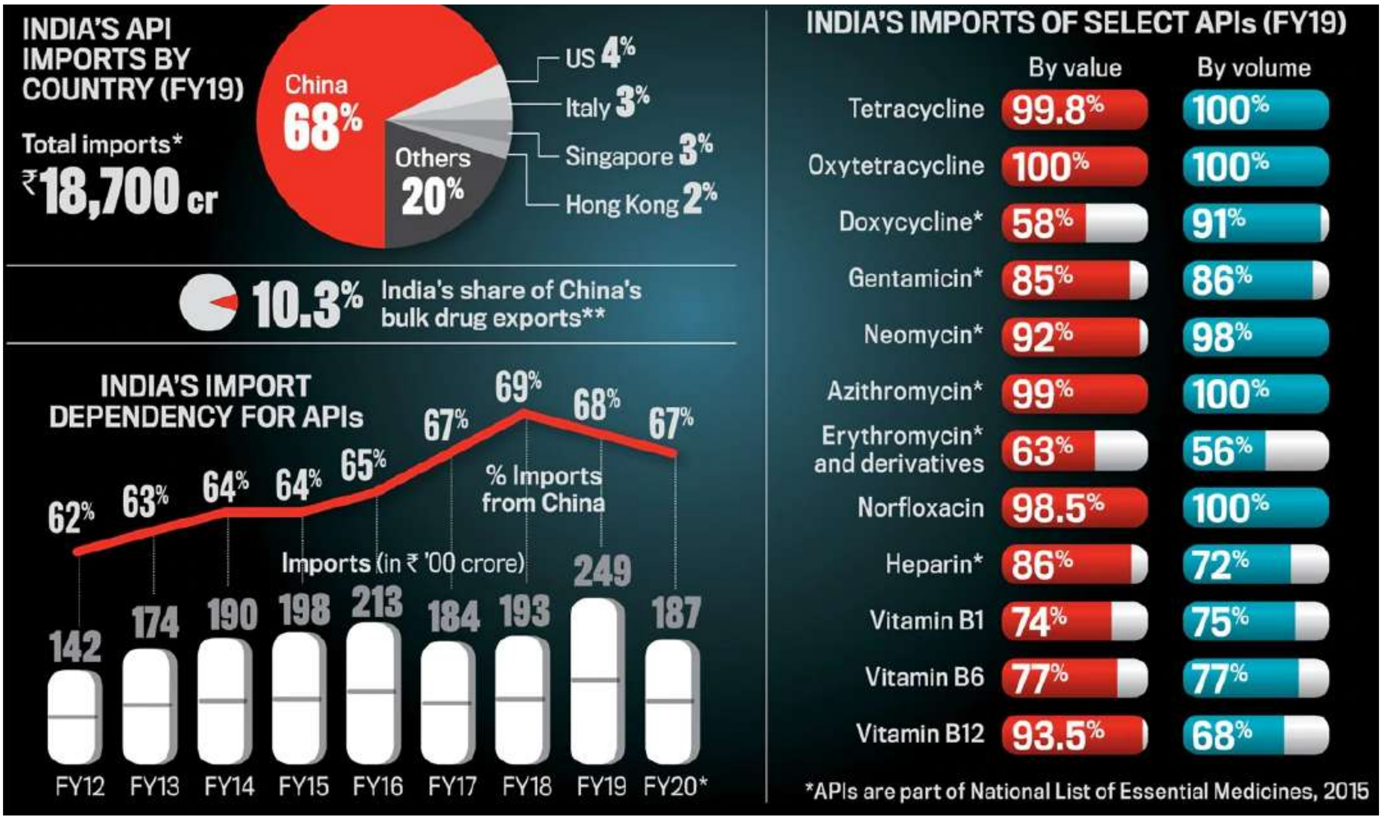
These are testing times for India's Rs 3.74 lakh crore pharmaceutical industry. Disruptions in the flow of active pharmaceutical ingredients or API (which are the building blocks of medicines), key starting material (KSM) and drug intermediates from China have made the industry wary. As of now, they are in two minds: whether to produce some of the material in India or turn elsewhere, perhaps to Europe, to source it, though it will be costlier. The rising cost of imported APIs has also hit cost of production and the margins of Indian firms. According to the commerce ministry, between March and May this year, there has been a 20 per cent increase in drug prices due to the impact of Covid-19.

India meets most of its API needs through imports from China. In 2018-19, APIs worth Rs 16,900 crore was imported, accounting for 67.6 per cent of India's total imports while API exports to China were worth a mere Rs 1,600 crore. This is a drastic comedown from the situation 25 years ago when much of the pharma industry's needs were met by domestic API production. However, as the Indian pharma industry moved up the value chain to make finished drugs, it began to rely more on China for low-cost raw material. Currently, domestic APIs (there are about 1,500 plants making APIs) accounts for just 10 per cent of the market. The government now plans tighter regulations and higher duties for imported Chinese APIs and KSM for medicines and even medical devices (China's share is about 11 per cent in this). It's also working towards reducing import dependence so that in case tensions worsen between the two countries, India's drugs security is ensured. India is also likely to source more APIs from Germany, Sweden and Italy. The Indian pharma industry is the third largest in the world by volume and 14th in terms of value.

Currently, India imports more than 53 critical pharma APIs, including those used in medicines for tuberculosis, steroids and vitamins, from China. Raw material include both API and inactive ingredients (excipients). The latter do not have direct therapeutic action but support or enhance drug stability/ bio-availability or patient acceptability.

China's API market has diversified to over 2,000 molecules and over 7,000 manufacturers, with an annual production capacity exceeding two million tonnes. Chinese products are 25-30 per cent cheaper than other markets and supplies are crucial because these are routine products used in high quantities. In 2019, China exported 10.1 million tonnes of APIs, up 8.83 per cent year-on-year, says data from the China Chamber of Commerce. The country exports APIs to 189 countries and is a leader in the sector, accounting for 20 per cent of the world's production. India's share in China's bulk drug exports was around 10.3 per cent in 2018 but is probably less now, says commerce ministry sources.





*Graphic by Tanmoy Chakraborty; *Apr-Dec 2019, **for 2018; Source: UN Comtrade (Source: KPMG/ CII)*

Dependence on China can be curtailed but cannot be wholly stopped, admit industry insiders. The long-term challenge lies in loosening China's stranglehold over strategic industries which supply inputs to Indian firms. Back in 2014 itself, the Narendra Modi-led NDA government had declared that it wanted to make Indian industry competitive in the area. In fact, 2015 was declared the year of the API with then Union minister Ananth Kumar saying the issue was a matter of national health security. Imports of APIs, though, continued to rise steadily. In 2019-20, it was worth Rs 24,900 crore, up from Rs 19,300 crore the previous year. Plans and initiatives to spur domestic manufacture have advanced at a slow pace till now.

> **10.3% India's share of China's bulk drug exports in 2018. It's probably even less now, say commerce ministry sources. China is a global leader in the segment, exporting to 189 countries**

From this month onward, the government will put into effect a Rs 7,000 crore production-linked incentive scheme aimed at promoting indigenous manufacturing of critical KSM, drugs, intermediates and APIs. It has identified 53 compounds, where imports are high, for manufacture in India such as those required for antibiotics, and medicines for heart ailments, diabetes, blood pressure and TB. It has also announced a 20 per cent incentive on the incremental sale of some products. The government will provide Rs 10 crore each to domestic companies to set up plants to produce 41 products covering the 53 crucial APIs. Incentives will be given on the condition that products be manufactured with complete backward integration and supplied only to domestic drugmakers. "This should be leveraged to lower import dependence and also keep prices affordable," says G.V. Prasad, chairman, CII national committee on pharmaceuticals and co-chairman and MD, Dr Reddy's Laboratories. "In the past few years, we have actively developed Indian sources based on price increases by China. That has helped partially. We will now do more to accelerate the development of inhouse sources as well as domestic sources for our raw material."

The department of pharmaceuticals has also announced a scheme for promotion of bulk drug parks. The scheme proposes to give grant-in-aid with a maximum limit of Rs 1,000 crore for a bulk drugs park or 70 per cent of a project's infrastructure costs. The scheme will be open till 2025.

Incentives are important in the case of the bulk drugs industry because it is capital-intensive and also needs huge tracts of land. Gujarat, Andhra Pradesh, Telangana and Tamil Nadu are already in the race to set up such parks. "A park with utilities such as a common effluent treatment plant will be attractive in terms of companies wanting to invest and build on scale," says Satish Reddy, president, Indian Pharmaceutical Alliance (IPA), and chairman, Dr Reddy's Laboratories. "We need to get the competitive edge back and it is possible only with a fully integrated chain."

Ground-level infrastructure, ease of doing business, shared facilities like pollution treatment plants to lower costs, will all be looked at before a final call is taken. "We need to examine alternative sources for APIs even if they are costlier," says Sudharshan Jain, director-general, IPA. But even if official clearances come by the end of 2020, it will be at least three years before the parks are up and running. "India can be an API and KSM hub, but for that to happen, we have to evolve a contract research and manufacturing services policy even as parks with advanced technology and stringent pollution norms come up," says Jayant Tagore, ex-president, Bulk Drug Manufacturers Association. Only then will India be able to meet the demands of both domestic and export markets.

Reducing the export-import imbalance, therefore, is still a long way off. However, Indian exports are growing. Total pharma exports increased 7.57 per cent y-on-y in FY20, to $20.6 billion or Rs 1.55 lakh crore. "Formulations apart, export of paracetamol and hydroxychloroquine in the wake of the pandemic too has driven exports," says

Pharmaceutical Export Promotion Council of India director-general R. Uday Bhaskar. Drugs and pharma exports in May rose to Rs 14,959 crore, up from Rs 11,758 crore in the same month last year. The demand for Remdesivir and Dexamethasone will further boost exports in the coming months. "Several countries are using anti-viral drugs, in which India is strong, to treat Covid-19," says Bhaskar.

Despite China's commanding position, it is both a beneficiary of Indian pharma imports and companies setting up offshore facilities or joint ventures there. Several Indian drugmakers already have their eyes on China. Aurobindo Pharma, for instance, is putting up an oral formulation manufacturing facility in Taizhou and has also entered into a joint venture. "Regulations have changed. Preference is there for FDA (US Federal Drug Administration) approved products and facilities in China," says Aurobindo Pharma MD N. Govindarajan. With the export potential high, more Indian companies may set up shop in China. The country gives extra incentives, including a three per cent export subsidy to make its pharma industry globally competitive.

India is yet to do any such thing to match the API sector that China has built with state support. Indian drugmakers need capital subsidy and big pharma players will need compelling incentives if they are to get back into manufacturing these bulk drugs.