



India's Increased Dependence on Chinese APIs Causing Concern



India's dependence on China importing active pharmaceutical ingredients (API) is the most among all countries, while national strategies to promote indigenous means of production continue to be relegated on paper. API is the most basic building block or component of a medicine. For example, acetaminophen or paracetamol is the chief therapeutic entity in Aspirin or Crocin brand of drug.

Latest statistics from Directorate General of Commercial Intelligence and Statistics tabled in the Parliament reveal that in 2016-17, of the total import totalling \$2,738.46 million (₹19,653.25 crore), China constituted 66.69 per cent (\$1826.34 million or ₹13,107 crore) of all bulk drugs and drug intermediates. In 2017-18, India imported \$2,993.25 million or ₹ 21, 481 crore worth bulk drugs and intermediates, and the share of China in the pie, increased to 68.36 per cent (\$2,055.94 million or ₹ 14, 755 crore). Chinese imports levelled at 67.56 per cent (\$2,405.42 million or ₹ 17, 263 crore) in 2018-19, still the largest share in total Indian imports worth \$3,560.35 million or ₹25, 552 crore. Also, overall India's dependence on imports has gone up by 23 per cent from 2016-17 to 2018-19.

Department of Pharmaceuticals (DoP) in Ministry of Chemicals and Fertilizers said that the imports from China are due to economic considerations, which essentially means that Chinese imports are cheaper and more cost-effective for pharma manufacturers.

In contingencies, such as the most recent one when lakhs of Chinese facilities remained shut for as many as two years to step up their environment compliance, and uncertainty loomed large over whether smaller Chinese units that were unable to comply with stricter norms, would open again, India looks at other sources like United States, Italy, Singapore, Hong Kong for import. However, there is always a fear of a sharp spike in finished drugs when APIs are imported from other countries apart from China.

And even as India's dependence on imports is considerable, policies formulated by government to minimize country's dependence on imports and to give fillip to indigenous manufacturing have remained only on paper.

It has been six years since 2013, when Congress had instituted a high-level committee for fighting the heavy Chinese dependence on bulk drugs. Later, National Security Advisor Ajit Doval had warned that Chinese dependence on API can be a national security threat. An official in Drug Controller General of India (DCGI) confirmed to Businessline, that apart from heavy dependence on legal imports, a large number of illegal imports of APIs from China were a cause of worry for the regulator.

In another reply tabled in the Parliament, DoP informed that an Inter-Ministerial Task Force was also constituted under the Chairmanship of the Minister of State (Chemicals & Fertilizers) on April 18, 2018 to formulate a road map for the enhanced production of Active Pharmaceutical Ingredients (APIs) in the country.

Sources in DoP told Businessline, that the task force has not even met every alternate month since August 2018, when ideally they are supposed to meet every month to take crucial decisions for boosting API productions in proposed bulk drug parks. DoP has a scheme - 'Assistance to Bulk Drug Industry for Common Facility Centre,' for providing assistance to Bulk Drug Industry for Common Facility Centre in any upcoming bulk drug park promoted by state governments or state corporations, the ministry has stated.

Only in-principle approval was given for constructing these parks till now in Himachal Pradesh, Telangana, Andhra Pradesh and Assam. It will still be a couple of years before the projects see the light of the day. (Source: Business Line)

US-China Trade War Opens Up Big Opportunity for India Pharma Sector, Says Dr Reddy's GV Prasad

The trade war between the US and China and the changed focus of the latter on its pharma sector, has opened up a big opportunity for the country's pharmaceutical sector.

GV Prasad, Chairman of CII National Committee on Pharmaceuticals and Co-Chairman of Dr Reddy's Laboratories, said that one out of every third pill consumed in the US and Europe is made in an Indian pharma company and the potential to scale up and address new areas of pharma sector is quite huge.

Interacting on the sidelines of a CII hosted Pharma Conclave, Prasad said, "Hyderabad has been a key pharma player contributing to global supplies. While it started with active pharma ingredients with IDPL playing a major role in developing the pharma ecosystem, later APIs and generics from Hyderabad and Vizag have grown significantly."

Apart from catering to the vibrant domestic market and global supplies, the country's pharma sector has the potential to scale up in the areas of biologics and vaccines.

Referring to how the trade war could have a positive aspect on the country's pharma sector, Prasad said, "several markets are not procuring from China and China has also decided to stepped up its game by addressing new segments within the pharma sector. And a number of Indian pharma companies are dependent on supplies from China."

"So now we have an opportunity to expand and initiate work on backward integration projects apart from setting up new facilities. This will enable us to add scale. However, there is need to meet stringent quality controls and the growing number of USFDA queries is an indication that pharma companies need to scale up, go digital and focus on Industry 4.0," he said.

On a number of pharma companies located in the urban areas, he said they need to shift to other locations. This requires deployment of significant new capital. Some of the companies are using old technology and they need to upgrade to stay competitive in the global marketplace.

He said that Government has been focussing on healthcare and affordability is a significant departure from the past. The Government is now seeking to own the healthcare of the citizen. "The cost of healthcare is amongst the lowest when we compare with other parts of the world. However, the real challenge is the affordability due to low income level of a major chunk of the population."

"As a country, we need to also look at the challenge of addressing lifestyle diseases. Given the progress we have made, those born around these years have the potential to live up to 100 years," he said. (Source: Business Line)

Sanofi CEO to Unveil New Strategy in December to Sell or Spin-off Consumer Health Unit

French drugmaker Sanofi is considering a joint venture or outright sale of its consumer healthcare unit as it readies its new strategic plan that is likely to be announced next month, a Reuters news report said.

Sanofi's newly appointed CEO Paul Hudson plans to meet investors for a capital markets day in Cambridge, Massachusetts, on December 10.

Also likely to figure in its new strategic plan is an initial public offering (IPO) of the consumer healthcare business, which could be worth around US\$ 30 billion, sources said. However, no final decision had been made so far, they added.

According to analysts, divestment or spin-off of Sanofi's consumer healthcare arm would enable the group to invest more in internal research. Revenue of the consumer healthcare arm grew by 3 percent at constant exchange rates last year to US\$ 5.2 billion (Euro 4.7 billion).

Sanofi may also take decision about the future of Sanofi's ailing diabetes business, which has been under constant pricing pressure in the US, while drawing up its new strategic plan. Hudson said last month he and his teams would study the performances of every Sanofi division to decide where to invest.

"Prioritization will become increasingly important going forward," Hudson had told reporters in October. "The reality in business is that some things are more important than others and we have to understand where we must win."

Meanwhile, Muzammil Mansuri, Sanofi's head of strategy and business development and member of the French drugmaker's executive committee, will be retiring from the company. This is the first major management change under Hudson, who took over on September 1.

Mansuri had joined Sanofi in 2016 from Gilead Sciences where he was in charge of research and development strategy and corporate development.

Hudson said in the memo that Alban de la Sabliere, currently head of business development, and Laurent Van Lerberghe, head of strategy, would take on more responsibilities as of December 1 and report directly to him. Even though the group's new strategy is still in the works, Hudson has made no secret that significant changes were underway. (Source: PharmaCompass)

Kids Up to 4 Are Main Victims of Antibiotics Over-Prescription



Of every five patients reporting common ailments, at least two patients end up being prescribed powerful antibiotics. Approximately, 51.9 crore anti-

biotic prescriptions were dispensed in the private sector, translating to up to 412 prescriptions for every thousand patients, reveals a study, Outpatient antibiotic prescription rate and pattern in the private sector in India: Evidence from medical audit data.

What is worrisome is that most of these antibiotics were given to children in the age group of 0 to 4. The average prescription rate was 636 per thousand patients in this age group.

According to the study, most of the prescriptions were for acute upper respiratory infections (20.4 per cent), unspecified acute lower respiratory infection (12.8 per cent), disorders of urinary system (6 per cent), cough (4.7 per cent) and acute nasopharyngitis or viral sore throat (4.6 per cent).

“Although clinical guidelines on judicious antibiotic-use explicitly mentions that antibiotics should not be prescribed for common cold, non-specific upper respiratory tract infection, acute cough illness, and acute bronchitis, literature from India indicates high rate of antibiotic prescriptions for respiratory infections in primary care,” notes co-author Habib Hasan Farooqi of the Indian Institute of Public Health, Gurugram.

Commonly prescribed

The authors argue that acute upper respiratory infections, cough, acute nasopharyngitis and acute pharyngitis are viral in origin and self-limiting. “Hence, in the light of evidence-based medicine and standard treatment guidelines, it may be argued that a significant proportion of these antibiotic prescriptions might be inappropriate. Previous research on prescription practices also highlighted the problem of inappropriate use of broad-spectrum antibiotics in India.” the study says

The paper states that prescriptions with cephalosporins and quinolones at 38.2 per cent and 16.3 per cent, respectively, in India were significantly higher than in the US (14 per cent and 12.7 per cent), and Greece (32.9 per cent and 0.5 per cent). “Up to 10 crore, or one-fifth, of antibiotic prescriptions were dispensed just for upper respiratory infections, which rarely require an antibiotic therapy,” the paper says.

The study argues that in India, not only is the prescription rate higher, but the choice of antibiotics for the treatment of uncomplicated respiratory infections too, was inappropriate. It notes that limited access to medicines in the public sector also results in over-the-counter purchase of antibiotics, which is a key cause of inappropriate use. (Source: Business Line)

Teva, Endo, Amneal, Bausch Among Top Companies Likely to Go Bankrupt says study



An analysis undertaken by BioPharma Dive has identified 31 troubled biopharma companies that are at highest risk of going bankrupt in the next 12 months. Amongst these are companies like Teva, Bausch Health, Endo International, Mallinckrodt and Amneal Pharmaceuticals. Also on high risk are small biotechs like Clovis Oncology and Puma Biotechnology.

BioPharma Dive used data from CreditRiskMonitor, a firm that calculates the probability that a company will go bankrupt in the next year using a 10-point scale called a FRISK score. The company says FRISK scores have been 96 percent accurate in predicting bankruptcy.

Though bankruptcy filings have typically been rare in the drug industry, they have ticked up this year primarily due to rising legal, political and market pressures.

Teva is the biggest company on the list. The Israeli drug-maker has struggled to chart a convincing path forward given its rising legal liabilities and eroding revenues. Teva also finds itself at the center of several prominent controversies.

Legally, Teva faces charges of helping spur an opioid epidemic and of conspiring to fix prices with other generic drugmakers.

In December 2017, hundreds of opioid-related court cases were consolidated into a case proceeding in the Ohio federal district court, with Teva one among many industry players facing charges. That led to a recent round of early settlements with two Ohio counties.

Along with these prominent legal battles, analysts have also voiced concern about Teva’s high debt levels, which stood at nearly US\$ 27 billion as of the end of September this year. (Source: PharmaCompass)

Mylan-Upjohn Combine to be Known as Viatris

Viatris, it is. More than three months after Mylan said it would combine with Upjohn, a division of Pfizer, the two companies have announced that the new combined entity will be called Viatris. “Deriving it’s name from Latin, Viatris embodies the new company’s goal of providing a path — “VIA” — to three — “TRIS” — core goals: expanding access to medicines, leading by innovating to meet patient needs, and being a trusted partner for the healthcare community worldwide,” a note from the company said.

Robert J Coury, who will serve as Executive Chairman of the new company, as indicated earlier, said: “We are creating a company unlike any other — a company focussed on building a more hopeful and sustainable healthcare journey, empowering patients to live healthier at every stage of life.”

Global giant

In July, US-headquartered Mylan had said that it would combine with Upjohn, Pfizer’s off-patent branded medicines business, to create a new global pharmaceuticals company. The mega transaction was expected to give the combined entity a foothold in China, besides bringing into its fold international brands such as Lipitor (for cholesterol), Viagra (erectile dysfunction) and Celebrex (arthritic pain), among others. “The name Viatris communicates the strength of our companies’ combined heritage and our shared goal to provide the highest-quality medicines to the most patients possible,” said Michael Goettler, Group President, Upjohn, who will serve as Chief Executive Officer of Viatris.

Viatris will unite Upjohn’s strong leadership position in China and emerging markets with Mylan’s significant presence in the US and Europe, allowing the new company to have a meaningfully expanded geographic reach for Viatris’ broad product portfolio and future pipeline.

Product diversity

In a recent interaction with BusinessLine, Mylan President Rajiv Malik had said that the transaction would diversify the product basket from generics to established brands, besides giving Mylan a strong foothold with Upjohn’s sales force into China, a fast growing healthcare economy. It would also give Mylan a critical mass in Korea, Brazil and Mexico, he added.

Responding to a question on whether the transformation into the new entity would involve a rationalisation of overlapping brands and employees, Malik said the rationalisation process had been under way in Mylan, given its acquisitions of established pharmaceuticals from Abbott (2015), Meda (2016) and Renaissance Acquisition holdings (2016). “We did not get time to sit down and rationalise. We started rationalisation last year,” he added, noting that a boutique consulting firm has been engaged to help navigate the course. “We are 55 per cent in generics and 45 per cent branded OTC (over the counter drugs)... we are a consolidated company,” he had said.

Shareholders of Mylan are expected to vote on the proposed combination of Mylan and Upjohn in the coming months. The new name will be effective on closing of the transaction, expected to occur in mid-2020. The two companies will continue to operate as independent, separate organisations until then. (Source: Business Line)

Novartis Agrees to Buy The Medicines Company for US\$ 9.7 Billion

Novartis has agreed to buy New Jersey-headquartered The Medicines Company (MedCo) for US\$ 9.7 billion. The buyout will give Novartis a late-stage PCSK9 therapy named inclisiran.

Inclisiran is a small, interfering RNA (siRNA) drug which works by blocking the synthesis of PCSK9 in the liver rather than targeting the protein itself. This allows more receptors on the liver cell surfaced to capture LDL cholesterol to break down. By lowering LDL levels (popularly known as the ‘bad’ cholesterol), the likelihood of major cardiac events decreases.

“The prospect of bringing inclisiran to patients fits with our overall strategy to transform Novartis into a focused medicines company and adds an investigational therapy with the potential to be a significant driver of Novartis’ growth in the medium to long term,” Novartis CEO Vas Narasimhan said.

According to MedCo, the planned approval for inclisiran is set to be completed before the end of the year in the US, and in Europe in the first quarter of 2020, With Novartis picking up MedCo, the rumor mill is abuzz once again. Amarin is said to be another target of a big acquisition with an FDA decision on a heart-helping label expansion for Vascepa coming late next month and prescriptions for the lipid-lowering drug on the rise.

Some bullish investors also think the MedCo deal for PCSK9 candidate inclisiran could spell a buying boom in the cardiology space. They believe an Amarin deal could be worth more than US\$ 20 billion, with suitors like Pfizer and Amgen speculated to be in the running. Amarin has not commented on these reports, which it terms as “rumour and speculation”. (Source: PharmaCompass)