

# Govt should grant infrastructure status to API industry: IPA President Satish Reddy

By CR Sukumar, ET Bureau Last Updated: Jul 27, 2020, 10:42 AM IST

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### Synopsis

The IPA wants the government to accord infrastructure status to the Active Pharmaceutical Ingredients (API) industry, and provide a boost to innovation through tax incentives on patent income, streamlined pathways for testing and approval of experimental therapies, its president, Satish Reddy told ET.



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*As India readies its plan towards self-reliance for key bulk drugs amid the Sino-Indian border stand-off, and the coronavirus outbreak, the Indian Pharmaceutical Alliance (IPA), the lobby body of domestic research-based pharmaceutical firms, seeks a supporting regulatory environment, ease of doing business and sops to boost investments. To build self-reliance on raw material, the IPA wants the government to accord infrastructure status to the Active Pharmaceutical Ingredients (API) industry, and provide*

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COVID-19 CASES		Confirmed	Deaths
India	World	3,167,323	58,390

*a boost to innovation through tax incentives on patent income, streamlined pathways for testing and approval of experimental therapies, its president, Satish Reddy told ET's CR Sukumar. Edited excerpts:*

### What challenges does the face-off with China pose for the Indian pharmaceutical sector?

India imported around 24,900 crore worth of bulk drugs in FY19, of which 68% was from China. Over 95% of API import for key drugs such as Paracetamol and Azithromycin are from China. From the standpoint of **generics manufacturers**, over-dependence on any one source or market poses a risk. Over the past couple of years, we have seen some price and supply shocks in the API space on account of pollution control-related shutdowns in China, and supply chain disruptions during the initial phases of the Covid crisis. Consequently, the Indian pharma industry needs to ramp up domestic manufacturing of APIs. To aid this, the government has recently announced a PLI scheme and earmarked around 3,000 crore to set up common infrastructure facilities in bulk drug parks. In addition, we need to work on

measures such as easing the process for environmental clearances, uninterrupted / low-price supply of utilities, and policy support in the form of tax incentives, favourable licence renewals, and capital subsidies.

### **How do you look at opportunities the face-off with China offer?**

We consider this to be the 'Year of the API'. While the pandemic has revealed the world's dependence on a single source for imports, the current scenario has strongly reinforced it. This has created an opportunity for the Indian pharmaceutical industry. The time is ripe for the industry to shift towards self-reliance and play a larger role in securing global drug supplies to cement its position as the pharmacy of the post-Covid world.

### **What regulatory bottlenecks do the Indian innovation-led pharma industry face with regard to clinical trials, drug approvals, production, pricing and export of Covid drugs?**

For a conducive innovation ecosystem, simplification of regulatory processes and timely approvals are vital, especially for early product introduction. For instance, multiple agencies are involved when it comes to product approvals and it takes 50-85 months in India, compared to 23-26 months in other countries. Creating a supportive regulatory environment and enabling ease of doing business helps in infusing long-term investment.

### **How can the Indian pharma sector capture the global market?**

India is the global leader for pharmaceutical products, especially generic medicines. We account for 60% of the global vaccine production, 25% of the demand for medicines in the UK, and one in three pills consumed in the US. The Covid crisis has also underscored the need for a research-based industry that is capable of quickly devising solutions especially in pandemic situations. Innovation should be given a boost with a combination of tax incentives, rebates on patent income, access to risk capital/grants, and streamlined pathways for testing and approval of experimental therapies.

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To boost investments in the Indian pharma sector, we need to work on aspects such as simplification of processes and guidelines for product approvals and the regulations (e.g. for clinical studies), and on a stable pricing environment that takes into account inputs from all relevant stakeholders across the value chain. Finally, easing price controls on drugs that cost less than Rs 5 per unit in the domestic market and providing incentives for exports will spur investments on both fronts.

### **What do expect the government should do to help industry consolidate India's position and emerge the pharmacy of the post-Covid world?**

The government needs to look at making the ease of doing business much better. Thus, the top four things would be: incentives, access to low-cost

capital, ease of doing business, especially in environmental clearances and reforms in price control.

### **What should the industry focus on?**

It is important that the pharma industry moves up the value chain by focusing on innovation and quality. The government has taken cognizance of the need to revive the domestic bulk drugs industry to address import dependence on a single source – this is a great first step. In the short term, formulation players in India must work to de-risk its single source/country dependency through the qualification of multiple, viable sources of API. Additionally, the industry must move from branded generic drugs to discovering and developing new drugs. For that, creating an enabling research system is a must.

### **What bottlenecks should the government resolve in manufacturing and distribution?**

The industry has seen a strong recovery. However, it is important to map out, and be cognizant of the logistics challenges faced in the early stages of the lockdown so that we can avoid such a situation in the future. The industry and the government must work together to define clear guidelines for potential bottlenecks/challenges such as the inter-state movement of goods, operation of airports /ports, operation of ancillary industries that support the pharma industry and availability of manpower.

### **What key benefits do you see with the infrastructure status for the API sector?**

The industry needs better access to capital for capital intensive sectors such as fermentation APIs. Loans available to the API industry are typically at higher interest rates and with short tenures. Granting infrastructure status to the industry will enable it to borrow money from insurance companies and other funds on longer 10-15-year tenures at very attractive interest rates. Gain access to foreign currency funding through the external commercial borrowing route. This would enable the industry to easily raise capital for investment in increasing capacity/infrastructure.

### **What incentives are you seeking for research?**

While India is a leader in the generics space, a significant portion of the value in the pharma industry lies in innovative products/new molecular entities. Consequently, it is very important for us to think about how to incentivise innovation in the country. Along these lines, some key incentives for companies that IPA is seeking are: tax incentives on R&D spends to be restored; favourable tax rates for patent income; increased and more streamlined government funding for innovation, across the entire innovation lifecycle and creating a vibrant innovation ecosystem to incentivise VC investments in early-stage pharma projects.

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