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INTERVIEW: SATISH REDDY, chairman, Dr Reddy's Laboratories

'Focus on API industry, cutting imports need of the hour'

The domestic pharmaceutical industry aspires to become the world's largest supplier of drugs, targeting $120-130 billion in revenue at a CAGR of 11-12% by 2030, from $38 billion at present. In value terms, it aims to improve the market share to 7% from the current 3.6%. **Satish Reddy,** *president of the Indian Pharmaceutical Alliance and chairman of Dr Reddy's Laboratories, in an interaction with* **BV Mahalakshmi,** *says there has to be a renewed focus on the active pharmaceutical ingredients (API) industry following the good manufacturing practices (GMP) regulations, and the need of the hour is to reduce dependence on imports. Excerpts:*

What is the role of domestic industry to global contribution in terms of value and volume?

The Indian pharmaceutical industry is the world's third largest in terms of volume. In the course of its journey to become a $38-billion industry, the domestic industry has reduced India's per person disease burden, measured in terms of DALY (disability adjusted life years), by 36% between 1990 and 2016, which is phenomenal. The lower disease burden was driven by reduction in infectious and associated diseases – from 61% disease burden in 1990 to 33% in 2016. Globally, we supply over 60% of global demand for various vaccines and anti-retro viral drug supplies, 30% of UNICEF's annual supply globally and about 60%-80% the UN's purchases of drugs. India contributes approximately 57% of APIs and 69% finished pharma products to pre-qualified list of the WHO.

What is the industry's contribution to the economy and vision?

The industry generates $11 billion trade surplus every year. It attracted $2 billion in FDI inflows during the last three years and is ranked among the top sectors attracting FDI, providing employment to over 2.7 million people. India needs to emerge as an innovation leader and take a globally-recognised position with both

incremental innovation and new molecular entities. It aspires to become the world's largest and most reliable supplier of drugs targeting revenues of $120-130 billion at a CAGR of 11-12% by 2030, from $38 billion at present. A stable pricing policy and supportive regulatory environment would encourage investments in India. There has to be a renewed focus on the API industry and need of the hour to reduce dependence on imports.

What are your views on price control and related pricing patterns?

There have been several changes on the pricing front and on the National List of Essential Medicines. While in volume terms, the Indian pharma industry is ranked third, in value terms, we are 11th. This is testimony to low margins and severe pricing pressure that we operate under. Furthermore, this is an industry where R&D of new products is time consuming and expensive. The industry needs support from the government to facilitate an environment that encourages investment in R&D and innovation.

What are the measures to increase API manufacturing to counter imports?

India continues to import a significant percentage of API requirements, primarily from China. There are several API units across India that run at less than 40% of capacity, against upwards of 65% in other parts of the world. This is a matter of concern. Over-dependence on imports leads to volatility in supply and pricing. The Katoch Committee recommendations for reviving the API industry, if implemented in spirit, could be a starting point to take this challenge head on.

What is IPA view on increased scrutiny by drug regulators?

The industry consistently follows stringent quality standards set by global and Indian regulatory agencies. Generic drugs that we manufacture undergo rigorous procedures to ensure the same quality standards as those of originator drugs. IPA companies have created targeted guidelines and best practices in areas of relevance: Data reliability guidelines, process validation guideline, good documentation guideline and investigations for non-conformities guideline. These have been vetted by regulators across the world.