**IPA Chief Reddy: Coronavirus API Supply Impact A 'Big Wake Up Call' For India**
by Anju Ghangurde

*Executive Summary*

Satish Reddy, president of the Indian Pharmaceutical Alliance and chair of Dr Reddy's Laboratories, tells *Scrip* in an interview that the government and domestic industry have to act promptly, and in tandem, to regain India's glory days of dominance in active pharmaceutical ingredients and avoid a public health problem.

The writing has been on the wall for several years now and the coronavirus situation has only highlighted what several industry veterans have long been saying – India's dependence on China for active pharmaceutical ingredients (APIs), intermediates and key starting materials is far too unhealthy for its own medicines security.

The country now accounts for an estimated 65-70% of total imports of APIs and intermediates into India.

Satish Reddy, president of the Indian Pharmaceutical Alliance (IPA) and chairman of Dr. Reddy's Laboratories Ltd., underscored that the current situation is a "big wake up call for India" and that the government and domestic industry need to work in alliance, and quickly, to regain some of industry's past dominance in the API space and avoid a public health problem.

"The government needs to step in if we have to move towards self-sufficiency and back to our glory days of dominance in APIs; interventions are required as this is a highly capital intensive area," Reddy told *Scrip* in an interview on the side lines of the recent India Pharmaceutical Forum in Mumbai.

The meeting, organized by the IPA, saw drug makers, regulators and other key stakeholders review and deliberate a host of critical issues pertaining to quality management and expectations around this. (Also see "India Pharma Forum: What The FDA, Indian Regulator Flagged Up" - Pink Sheet, 2 Mar, 2020.)

IPA members account for over 80% of India's pharma exports and also cater to more than 57% of the domestic market.

Incentivization Needed

Reddy said that unless government policy initiatives and "some sort of incentivization" work in tandem with the pharma industry wanting to get back into the space, "we will never find a solution to this." Industrial parks, central common utilities, and some level of financial incentives for firms to get back into this space are vital, Reddy emphasized.

Incentives might include some level of tax breaks for a defined period, suggested the executive, who is the son of industry doyen and Dr Reddy's founder Anji Reddy, who died in 2013.

The Indian government, including the Prime Minister's office, are said to have seized on the API supply chain disruption issue against the backdrop of the coronavirus outbreak that started in China, and the

indications are that the government think-tank NITI Aayog, the Department of Pharmaceuticals and the finance ministry have been putting together a plan to revive India's API segment.

Over 30 drugs for which action is to be prioritized have already been identified, with local media reports suggesting that an outlay of INR30bn ($407m) is being finalized to support industry. Indications are that professional services firm PwC may also be also engaged in preparing some inputs on the issue, though there is no official confirmation on this.

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On 3 March, India notified a list of APIs and formulations, including paracetamol, tinidazole, metronidazole, for which exports have been restricted, with immediate effect. (Also see "India Curbs Exports Amid Coronavirus" - Generics Bulletin, 4 Mar, 2020.) (Also see "India Acts To Limit Supply Disruption From Coronavirus" - Scrip, 24 Feb, 2020.)

## Getting Back To Global Leadership

IPA president Reddy, however, said that India's efforts to become self-reliant for APIs should not be seen through the narrow lens of just the evolving coronavirus situation.

"The objective should be that the Indian API industry should get back to global leadership in most of the molecules, as was in the 1990s. If we have to operate in that scale, it can't be left to industry alone. It requires a mix of policy, infrastructure support, some incentives."

The Indian pharmaceutical industry, especially for bulk drugs, was well ahead of that of China until the 1990s. In fact in the mid-90s, India was one of the largest producers of sulfa drugs, anti-tuberculosis treatments, antimalarials, paracetamol, ibuprofen and ciprofloxacin, among others. But certain unfavorable policy initiatives, including a reservation policy for certain products, saw investment interest decline and things turn counterproductive, eventually leading to huge import dependence.

Chinese pharmaceutical firms meanwhile, backed by their government, capitalized on the opportunity, helped by large fermentation units to mass produce bulk drugs and intermediates, alongside establishing facilities for producing these products by the chemical synthesis route. A 2014 white paper by the Indian Drug Manufacturers' Association highlighted the closure of more than 10 fermentation API units in India, including those for gentamycin, pravastatin, cyclosporin A, cephalosporin C, bleomycin and vitamin B12 between the early 1960s to the late 90s, against the backdrop of the surge in Chinese imports over the years.

"As a result of some policy actions and then the lack of timely interventions from both the government and industry, we ended up ceding the entire API space," Reddy lamented.

## Past Initiatives

There have been some past attempts to galvanize action, though with limited follow through so far. In 2013, the government constituted a high level committee, led at the time by V M Katoch, a former director general of the Indian Council of Medical Research and secretary, department of health

research, to study and identify APIs of critical importance, and to work out a package of interventions/concessions required to build domestic production capabilities and examine cost implications.

The committee made a range of recommendations, including the establishment of "mega parks" for APIs with common facilities, and proposed financial investment from the government for the development of clusters, possibly in the form of a professionally managed, dedicated equity fund for the promotion of manufacture of APIs, and extending fiscal benefits to create community cluster and individual unit infrastructure. (Also see "China API Juggernaut Rolls On But Can India Recoup?" - Scrip, 22 Dec, 2017.)

India's ministry of chemicals and fertilizers had, in fact, declared 2015 as the "Year of Active Pharmaceutical Ingredients", with then minister Ananth Kumar (now deceased) assuring the pharmaceutical industry that "appropriate decisions" will be taken to ensure that India becomes self-sufficient in bulk drugs. A bulk drugs policy has also been in the works over the years.

## Getting Into Manufacturing Space Quickly

For now though, things appear somewhat manageable since Indian companies have API inventory in place and "we don't have a crisis in terms of availability, at this point of time," Reddy said.

"But will this continue? We don't know. What if this [coronavirus] situation spirals out of control since there seems to be an uptick? While we hope things will be contained, the important thing is production getting back to full capacity in those countries post this inventory getting exhausted," he cautioned.

He also referred to another worrisome factor – that prices will start to increase, so the costs of firms will also go up, impacting corporate margins. "Our fervent hope is that things get back to normal and production can scale up to its original level."

On what could potentially be the worst case scenario, Reddy said that he's "not so pessimistic" and that it's important to note that Indian companies have the capabilities/technology to manufacture all the drugs that they import.

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"The question is getting into that space quickly on one side; when pollution control measures were implemented in China, companies like ours were always looking at alternative sources. But the whole issue centers around cost – that's key. I won't worry too much about capability/filling in the gap etc," he said. (Also see "China API Alert, Indian Firms Brace For More Pain" - Scrip, 3 Jul, 2018.)

## Shared Onus On Marketers For Quality

The Dr Reddy's chair also touched upon some other key industry issues such as the new rules in India that require marketers to share the onus for the quality of a drug, as well as other regulatory compliances alongside the manufacturer. (Also see "India Regulatory Diary: Marketers Co-Accountable For Lapses In Manufacturing Quality" - Pink Sheet, 17 Feb, 2020.)

Reddy said that it is a good provision for industry in terms of overall accountability and responsibility, adding that firms such as Dr Reddy's which have third party manufacturers for some products in any case make sure that "we have adequate controls through the entire chain."

"So, its anyway something that we follow as part of our global quality management system and not just in India, even in the US. Ultimate quality rests with us, for which you have to ensure that your systems are in place," he explained.

On the scope of compliances covered and the risk of marketers being faulted for serious issues such as data integrity at the third party site, Reddy said that while some dialog is underway with the government, unless you raise quality systems and have those standards across the sector, industry will never reach the level that is being sought.

"At this point in time, unless you start putting regulations in place, it [responsibility] will fall in no-man's land. But I agree it also has to be a bit calibrated, so that it doesn't lead to adverse consequences."

He also indicated that industry bodies like the IPA are in favor of making the Uniform Code of Pharmaceuticals Marketing Practices mandatory, adding that the industry association has adopted the voluntary code and has been adhering to it.

"It gets to a situation when you can't just expect industry associations to enforce that – not everyone is covered by such associations. So, at this point we are saying that if you have to make it mandatory, do so," he said.

But the hope is that things are not taken to the other extreme, imposing an unnecessary "administrative burden" on companies. "So we are saying make it practical," Reddy said.