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Countering the Chinese threat

By Prathiba Raju on September 22, 2016

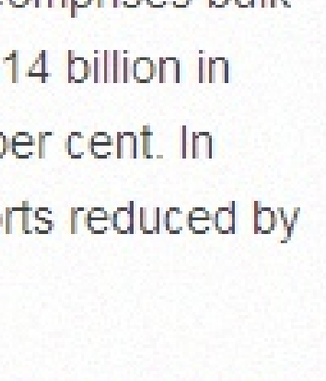
With the Indian government coming up with a slew of measures to counter the Chinese invasion in bulk drug manufacturing, can drug manufacturers in India make the most of it and become self sufficient ***By Prathiba Raju***

At a time when China is leveraging its bulk drugs or Active Pharmaceutical Ingredients (API) production, Indian pharma companies are lagging far behind. Indian generic drug manufacturers are unable to deliver the desired quantities and if prices are not favourable, supplies will be restricted. According to industry experts, this could have an impact on the country's competitiveness and its objective to become a global generic pharma power hub would remain a distant dream.

KV Subramaniam

"Dependence on China for APIs and advance intermediates is undoubtedly very high. From less than one per cent in 1991, the percentage of API imported from China had reached almost 60 per cent in 2011. If one accounts for the import of advanced API intermediates, then this number would be even higher. This presents a significant risk to the industry," said KV Subramaniam, President, Reliance Life Sciences.

A joint report by Boston Consulting Group (BCG) and Confederation of Indian Industry (CII), states that India depends heavily on imports. Nearly 80 per cent of many key raw materials (mostly intermediates and some API) are imported from China, which are used to manufacture at least 12 essential drugs. Some of these are paracetamol, ranitidine, ciprofloxacin, metformin, acetyl salicyclic acid, ofloxacin, metronidazole, ampicillin, amoxicillin and ascorbic acid.

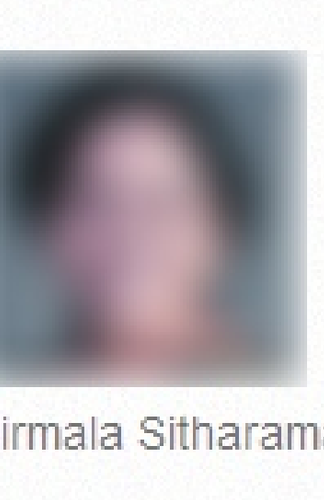


Utkarsh Palnitkar

"India is considerably dependent on Chinese imports for many APIs that are required to manufacture essential drugs listed in the National List of Essential Medicines (NLEM) 2015. Data analysis reveals that the value share of China in India's import of a few key bulk drugs — such as 6-APA, DCDA, PAP and Pen-G— is between 98 and 100 per cent. Given the critical nature of the formulations derived from these APIs, any adverse circumstances between the two countries could potentially lead to a health security risk in India. For example, during Beijing Olympics in 2008, China closed down several API plants, leading to a 20 per cent rise in the price of bulk drugs that we were sourcing primarily from China. Therefore, India needs to build a viable ecosystem to support the growth of bulk drug industry and achieve self – sufficiency at least in the strategically important drugs," said Utkarsh Palnitkar, Head – Lifesciences, KPMG India.

According to CRISIL research database on bulk drugs, the API market in India comprises bulk drugs for exports and bulk drugs for internal consumption. It was estimated at $14 billion in 2015-16 and is expected to reach $25.4 billion by 2020-21 with a CAGR of 16 per cent. In 2015-16, domestic consumption remained almost flat in dollar terms, while exports reduced by almost four per cent year – on – year.

But even though Chinese API manufacturers have captured the lion's share of the API market, Subramaniam hints at a ray of hope saying, "The pharma industry in India is estimated to have revenues of $30 billion, including exports. API currently forms a very small part of this. Only complex APIs continue to be manufactured in India because of the complexity and quality involved in the drugs' development and manufacturing. India has a competitive advantage of having broad and deep knowledge of science associated with API and formulations. This, coupled with recent thrust by the US and European regulators for quality and adherence to GMP norms, gives India a significant advantage in competing with Chinese suppliers. The only area of concern is the scale and cost competitiveness."

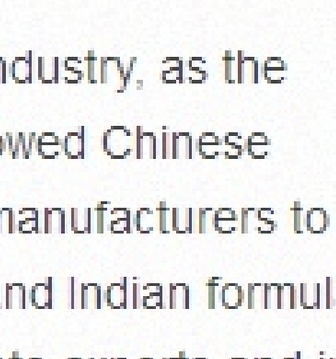


Ajit Kamath

Displaying the same optimism, Ajit Kamath, CMD, Arch Pharmalabs, highlighted that two decades back, India was self-sufficient in bulk drug capabilities and capacities. He is confident that even today, India can outdo most other countries in API manufacturing and can easily wrest back a sizeable market share what was conceded to China in the last 20 years."

"India's strength in API manufacturing can be gauged from the fact that India has the largest number of API sites that are approved as compliant by global regulatory agencies like USFDA, EDQM, PMDA Japan, TGA Australia, UK MHRA, Korean FDA. A proper financial and policy support to existing Indian API players itself would neutralise much of China's strength today," Kamath added.

View from the top



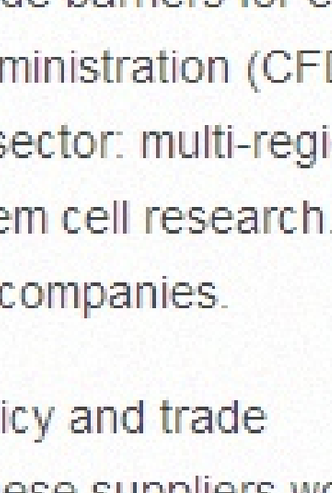
Nirmala Sitharaman

Talking to *Express Pharma* at Idea Exchange, organised by Indian Express, Union Commerce and Industries Minister, Nirmala Sitharaman, said, "API is a very critical issue. Gradually, we have lost contribution in API because cheaper imports are coming in from other countries. Now, this has a very big message, not just for pharma but to all the raw material-dependent industries, that manufacturing is crucial. We (the government) are conscious of their problems and realise that lack of API base in India is very concerning and we would like to do something," said Sitharaman.

Though India has a significant advantage to become a preferred source of API for customers worldwide, it needs stringent trade barriers to thwart China's dominance in the bulk drug market, observed experts.

Combating the bulk drug dragon

In a way, India has helped China grow and become more competitive in API industry, as the country's policies for registering APIs have been import-friendly. This has allowed Chinese manufacturers to dump their APIs in India at cheap rates, forcing Indian API manufacturers to shut shop. Moreover, anti-dumping duties in India is a long drawn out procedure and Indian formulation companies themselves don't support it. Incentive schemes by China to promote exports and in some cases additional incentives for certain families of drugs (like HIV, oncology, statins etc) make the Chinese manufacturers more competitive.



SV Krishna Prasad

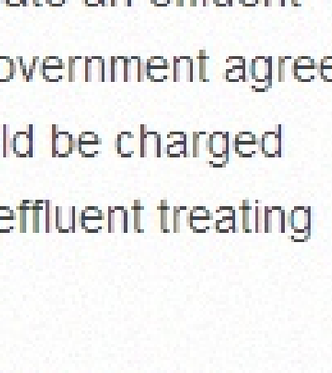
"Currently, import regulations of bulk actives in India are not as stringent as what the Chinese government have set for their own industry. Recently, Pharmaceuticals Export Promotion Council of India approached Union Ministry of Commerce and Industry to bring in stringency in order to encourage domestic manufacturers and also to curb indiscriminate dumping especially from other APAC nations. It is a well known fact that India has better infrastructure and quality complaint bulk drug manufacturing facilities in the country in comparison to those in China. However, India is yet to match its productivity with that of China. There is no reason why India cannot move past China and Italy to garner a top position in the world's bulk drug market with its additional quality of excellent communication skills in English. Hope, the latest FDI policies would trigger huge investments into the country bringing in financial, technological, R&D initiatives," said SV Krishna Prasad, CEO, CITO Healthcare.

The Chinese have excelled in bulk drug manufacturing as they have huge trade barriers for export of medicines and APIs. Over the past few months, China's Food and Drug Administration (CFDA) has brought out reams of new regulations on far-flung corners of its pharma sector: multi-regional clinical trials, biosimilars, drug evaluation and approval, and most recently, stem cell research. The increased bureaucracy around marketing approval applies mainly to foreign companies.

According to industry experts, if India doesn't put in place similar stringent policy and trade barriers, despite having world-class assets and conceded market share, Chinese suppliers would dictate price in the future, which will pose a threat to Indian players.

Pharma companies in India were forced to evolve business strategies to cope with skewed policies. Relating the sequence of evolution, Palnitkar said, "Over the last few decades, many Indian manufacturers have moved up the value chain to focus on commercially attractive segments such as finished formulations and complex-to-manufacture APIs. Local players thus started sourcing raw materials and simple APIs from cost-competitive locations, especially China. China, with its large manufacturing base of pharma intermediates and APIs, has been able to supply at a much lower cost than local companies. Over a period of time, our dependence on China resulted in a further increase of imports and unfortunately in shutdown of many manufacturing units in India, which simply could not compete with the Chinese firms. This spiral, has over a period of time, led to a complete dependence on China for some bulk drugs."

According to industry experts, factors which adversely affect India's API industry are high working capital costs, rising capital costs for setting up and expansion, restriction of foreign investment in the sector, unfavourable excise duty structure, power and utility costs, which are much higher than in China and lack of sufficient common effluent treatment plants.



Ajay Saxena

"One of the core issues that the bulk drug industry face is constantly changing environmental policies adopted by states. A fixed long – term environmental norm and common effluent treatment plants will help the industry in many ways," said Ajay Saxena, Director, Bulk Drug Operation, Rusan Pharma.

"The Central Government is supporting bulk drug manufacturing by encouraging to come out with common effluent treatment plants, which is crucial in APIs," informed Sitharaman.

The minister informed that she had taken the initiative and organised a meeting with Ananth Kumar, Minister of Chemicals and Fertilizers, and Prakash Javadekar, who was then the Minister of State (Independent Charge) Environment, Forest and Climate Change, where problems of bulk drugs manufacturers were discussed.

"Many bulk drug manufactures voiced their concern on how each one had to create an effluent treatment capacity and how a connected facility would help if provided. So the government agreed to set up common effluent treatment plants where small and big companies would be charged differently. The government will spend around Rs 300 crores to set up common effluent treating plants," informed Sitharaman.

According to bulk drug manufacturers, to make India less dependent on China, a few trade barriers should be implemented on imports. For instance, the process of registration of drugs in India should be as tough as it is to register drugs in China. API manufacturers from China should furnish proof that drugs supplied to India are approved by China FDA for both supplies to Chinese formulation or finished dosage from companies. Anti-dumping duties need to be invoked to protect Indian manufacturers. Tax incentives and re-aligning excise duty structure on local bulk drug manufacturers will ensure competitiveness to both API and formulation companies and incentives should be given to Indian formulation companies, rather than from Chinese importers.

Stringent trade barrierscan be adopted only with a robust policy. Thus, a specific policy focused on bulk drug manufacturing needs to be implemented immediately, urge industry veterans.

Robust policy need of the hour

In order to battle the Chinese bulk drug dragon, the Indian government is working on a new indigenous bulk drug policy, which is expected to enhance growth in the API market.

A senior official from the Department of Pharmaceuticals, Government of India, while speaking to *Express Pharma*, on condition of anonymity, said "The pharma sector offers huge opportunities for growth. The Central Government is working in that direction and are in consultation with all the stakeholders, including state governments. A Cabinet note on bulk drugs has been moved, which is based on the recommendations by the Katoch Committee."

VM Katoch

Talking about the recommendations, VM Katoch, who headed the committee says, "The committee report aims to make the API industry viable, self reliant and growing, which will successfully overcome the competition from other countries. As a result, India will maintain leadership in pharma sector which is critical for the health of our people. Our committee recommended self-reliance in respect to antibiotics, pain killers, anti-cancer drugs, anti – hypertensive drugs, anti – diabetic drugs and vaccines that may be considered to be of public health priority and emergency life saving drugs."

"In the API market, India stands third in the Asia-Pacific region. The main competition is from China. India's API market share has been witnessing a gradual growth over the years. The market share in 2005 was 6.5 per cent and was given a projected growth rate of 33.3 per cent by 2015. Exports of generic APIs have also seen an increase with 18.9 per cent between 2005-2010," said Prasad.

"Looking at the government's vision to accelerate growth in this sector, the policy is expected to address most of the challenges faced by the sector, and is certainly a step in the right direction," Subramaniam said.

Many Indian firms dealing with APIs have made consistent efforts to gain credibility in the regulated markets by improving their standards and seek approval for manufacturing facilities, therapeutic applications and products. Government support is need of the hour, stressed industry experts.

"The proposed bulk drug manufacturing policy which is expected to relax environmental clearance norms and enable easier financing regulations for bulk drug manufacturers will provide a conducive ecosystem to enable growth of this vital industry. The proposed policy is also expected to facilitate cluster – based growth with key announcements such as establishment of bulk drug mega parks, availability of land at concessional rates, access to continuous power supply at reduced rates, tax concessions and income tax benefits to manufacturers, provision of soft loans, and establishment of common infrastructure. Upon implementation, these provisions would collectively trigger investments in the API segment. Revived government focus may also lead to steady inflow of investments in the sector boosting India's bulk drug output," opined Palnitkar.

Constant upgrades in the quality of products and cost effectiveness have catapulted the growth of Indian API market globally. But, a robust policy, which improves the manufacturing standards, would go a long way to revive the manufacturing industry and put in a different phase of growth.

"We would like to see development in clearing policy guidelines, faster decision making, government's role as a facilitator, common effluent treatment plants so that industry can concentrate on manufacturing, research and development and new markets," said Saxena.

Stating that the national policy on bulk drugs is quite ambitious, Prasad said that major investments are involved in land acquisition, facility design and construction, equipment plan, procurement installation. He also indicated that the operations part also need huge capital investments.

Experts said that the new policy should bring in reforms by providing both infrastructural and financial support to the industry.

"We expect concrete steps that will help the sector increase its scale of operations and reduce operating costs to become competitive in the domestic and international markets. Relaxation in clearance norms, stringent guidelines for good manufacturing practices, a single-window clearance system that removes duplicity and ensures faster approvals would be welcome changes," Palnitkar added.

"The new bulk drug policy can help in giving the right messages and right support to those sectors which need them, and in this case to get into the specifics, which is getting APIs within India, I think there should be a concerted effort over and above the policy," Sitharaman stated.

The Centre's 'Make In India' policy has given a major boost to API manufacturers, which will help to boost the morale of the industry and that of the investors, informed experts.

Make in India to propel bulk drug sector

The imminent manufacturing policy supported by the 'Make in India' initiative is expected to trigger manufacturing activity in the bulk drug industry. Prime Minister Narendra Modi's pet initiative will create a comprehensive environment for bulk drug manufacturing industry.

"Bulk drug manufacturing is indeed in line with the 'Make in India' initiative as it not only makes India self-reliant in bulk drugs, but also helps to increase exports to commercially attractive regulated markets. The government has taken tangible measures in this regard by withdrawing exemption of customs duties given earlier to certain categories of drugs and bulk drugs. The government had earlier declared '2015 – Year of Active Pharmaceutical Ingredients' to build confidence in the industry and the policy is expected to be a significant push in this direction," said Palnitkar.

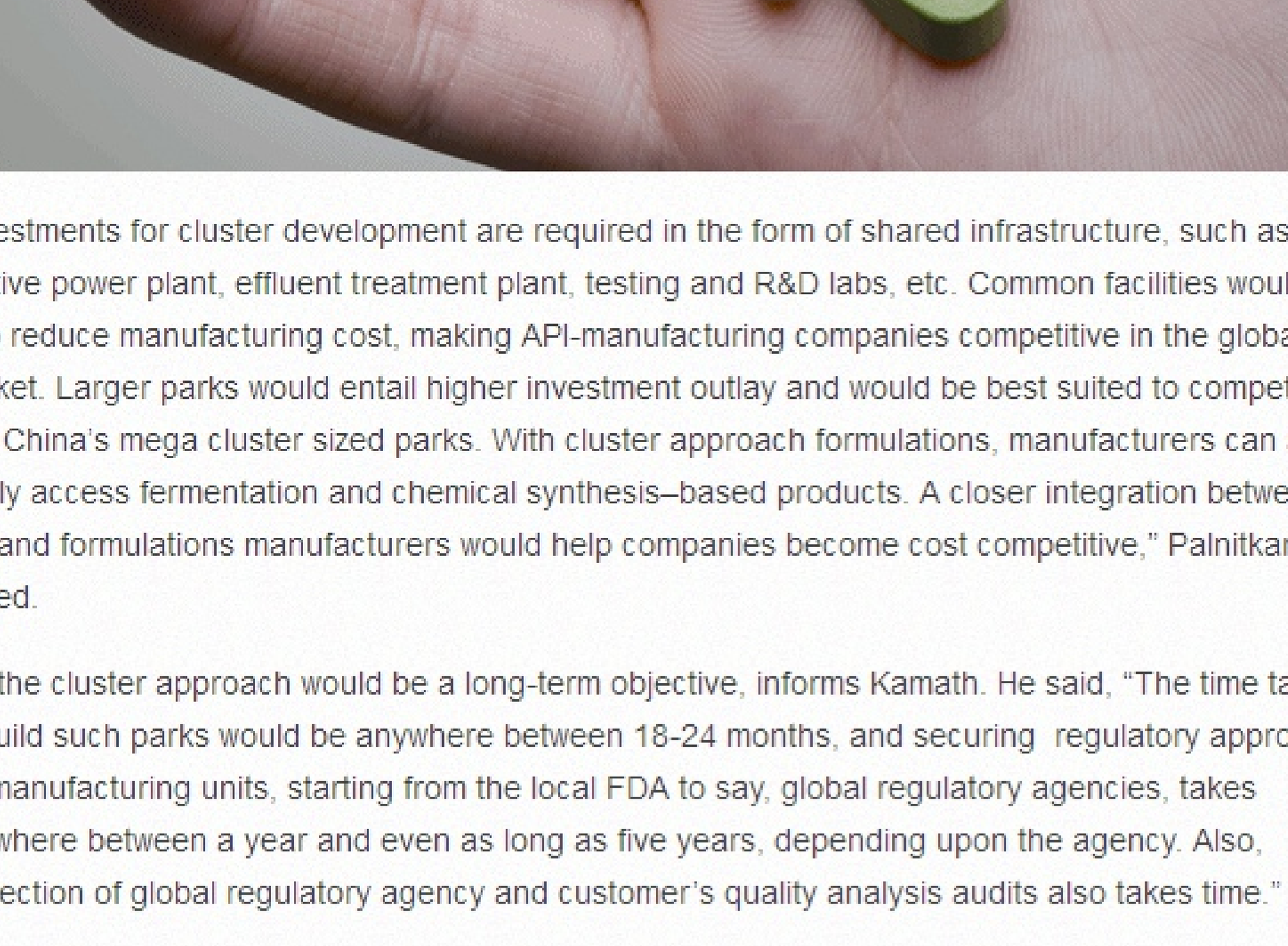
The new bulk drug policy with the 'Make In India' policy needs to be adopted with a cluster approach to further enhance it, urged industry experts.

"A cluster approach with common facilities will definitely bring down costs at levels lower than China. It will be appropriate for attaining progressive self-reliance and also for optimal utilisation of resources. For economising production, establishment of Large Manufacturing Zones (LMZs)/ mega parks for APIs with common facilities maintained by a separate Special Purpose Vehicles (SPV) will be most effective approach," said Katoch.

Giving an estimate, Katoch indicated that an average cluster will require about 1000 to 2000 hectares of land, which will require a minimum of Rs 1000 crores. He added that larger the cluster, bigger will be the returns and scope for larger number of players.

"I'm not against mega parks as long as they comply with the existing environment regulations. Now regulations have become even more stringent," said Sitharaman.

According to KPMG, bulk drug manufacturing companies need large scale operations to achieve economies of scale and provide cost – effective raw materials.



"Investments for cluster development are required in the form of shared infrastructure, such as captive power plant, effluent treatment plant, testing and R&D labs, etc. Common facilities would help reduce manufacturing cost, making API-manufacturing companies competitive in the global market. Larger parks would entail higher investment outlay and would be best suited to compete with China's mega cluster sized parks. With cluster approach formulations, manufacturers can also easily access fermentation and chemical synthesis–based products. A closer integration between API and formulations manufacturers would help companies become cost competitive," Palnitkar added.

But the cluster approach would be a long-term objective, informs Kamath. He said, "The time taken to build such parks would be anywhere between 18-24 months, and securing regulatory approvals for manufacturing units, starting from the local FDA to say, global regulatory agencies, takes anywhere between a year and even as long as five years, depending upon the agency. Also, inspection of global regulatory agency and customer's quality analysis audits also takes time."

As increasing dependence on China for API is posing a major threat. A long-term strategy to build bulk drugs parks might not immediately mitigate the present day risk. Thus, manufacturers emphasised that in the short term, the focus should be to improve competitiveness in domestic manufacturers and revive existing financially stressed bulk drug manufacturers. This will help save thousands of crores of fresh capital investments later down the line. A new bulk drug policy with stringent trade barriers is sought by the existing Indian API players to neutralise the Chinese bulk drug strength.

Thus the need is for both short term measures to ease the immediate pain, while preparing a long-term policy. But just as Band-Aid do not fix a long festering wound, different ministries and industry will have to get ready for a major overhaul for the API to survive and thrive against the competitors like China and Italy.

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