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“Govt is not extending support to SMEs dedicated to producing high-quality medicines that cater to the healthcare needs”

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With five decades of experience in the industry, and also as one of the founder members of the Pharmaceuticals Export Promotion Council of India (Pharmexcil), set up in Hyderabad in 2004, Dr P V Appaji served as the Director General (DG) of Pharmexcil from 2004 to 2016. During his term as DG, India witnessed the growth of pharma exports from $3.3 billion in 2003-04 to $14.6 billion in 2012-13. In an interaction with BioSpectrum India, Dr Appaji shares his views on the recent ‘Cough Syrup’ debacle and India’s dependence on excess imports of Active Pharmaceutical Ingredients (APIs) from China.

How do you view the recent episode of Indian ‘Cough Syrup’ exported to some African countries, which killed small children after consuming it? Do you think our industry and regulators failed to meet the drug safety standards?

The recent tragic incident involving cough syrup causing deaths of children in Gambia is a deeply unfortunate event. However, it is important to note that over 99.9 per cent of Indian pharmaceutical exports supplied to international markets adhere to rigorous and highly intricate international quality and safety standards.

In the case of the recent cough syrup incident, it was not the drug itself that caused the fatalities but rather an excipient known as propylene glycol, commonly available in two forms: pharmaceutical grade and non-pharmaceutical commercial grade, the latter containing dangerous toxins that can harm the kidneys. The cough syrup in question was reported to have used non-pharmaceutical grade Ethylene Glycol and Diethylene Glycol. I believe the failure to detect this irregularity can be attributed to the manufacturer, testing chemists, and drug regulators. It seems they may have focused solely on the effects of the drug within the syrup and overlooked the impact of the excipient. It's worth noting that such incidents have been reported in India in the 1970s, specifically in Maharashtra and Jammu & Kashmir, and even in the USA in the 1930s, where cough syrup toxins were linked to deaths.

In India, the Lentin Commission was established to investigate cases of children's deaths following the consumption of cough syrup, and it offered recommendations and suggestions. Despite these previous incidents, it appears that the development of Standard Operating Procedures (SOPs) was neglected. There were no alerts from regulatory authorities, manufacturing chemists, or quality control testing facilities regarding the dangers of these products. Furthermore, specific tests for the presence of ethylene glycol or diethylene glycol in finished cough syrup products were not prescribed. It appears that this issue was overlooked, and there was a lapse on the part of our regulators in identifying it.

However, following this incident, the government has taken immediate steps to rectify these oversights, including conducting awareness programmes among regulators, industry professionals, and quality testing experts to ensure such issues are addressed in the future.

Do you think that this incident has any impact on India’s pharma industry’s image and its exports in the international market?

Definitely not, this incident is an isolated case. Recently I have been to the CPHI Barcelona conference. I had the opportunity to meet various pharma industry leaders there, and many are aware of India’s capacity and capability as a quality global generic pharma manufacturer. They too identified this cough syrup incident as an isolated case and not many expressed their apprehensions on the overall capability of India’s pharma sector. However, as a responsible country, India needs to rectify the lapses and accordingly, even the regulators have taken steps to correct the gaps. The pharmacopoeia had identified and headed this issue. Regulators have also been alert. And even the Union Minister visited Hyderabad and conducted a brainstorming session with all stakeholders including leaders from National Pharma Industry Associations, Drugs Controller General of India and state Drug Controllers and key decisions were taken to further strengthen the drug regulatory system.

As per the discussions, it is learnt that the government has decided to take up Risk Based Inspections regularly and accordingly will conduct inspections based on prior data, by testing sample collections and based on complaints and alerts indicated by regulators during the WHO GMP inspections.

Overall, our regulatory system is further strengthened to ensure that all necessary quality and safety standards are followed during the manufacture of drugs and medicines in India.

What steps have been taken to improve the bulk drug sector and reduce India’s dependence on excess imports of Active Pharmaceutical Ingredients (APIs) from China?

Right from the beginning, the Government of India has been taking up various initiatives to support and extend a helping hand to lift the Indian pharmaceutical industry in the right direction. Particularly concerned with the issue of the industry’s excess dependence on imports of low-cost APIs from China, India has introduced the Production Linked Incentive (PLI) scheme recently. Earlier also many assistance programmes were implemented. However they did not yield much due to a lack of transparency. In the wake of this, the government of India has brought out a well thought of PLI Scheme. This scheme’s main aim is to strengthen our self-dependency and overcome the threat from our major competitor China.

The government has recently published the revised PLI scheme and has come out with a proposal for supporting the production of 42 major identified products including APIs, Drug Intermediates and Fermentation products under the PLI scheme. For which the government has put aside Rs 15,000 crore budget to be spent over six years.

The biggest tragedy for our country is the lack of domestic sourcing of fermentation products, which India and the whole world are heavily dependent on China. If China stops these key basic raw materials, not just India, the entire global pharma industry will starve.

Keeping this in mind, India has taken bold steps in the form of PLI schemes to make the industry develop its strength and to stand on its own feet to compete with our major competitors like China in the coming days.

Unlike earlier schemes to provide grants, the PLI scheme is very good, transparent and more accountable as incentives will be provided to the concerned manufacturer only if the promised quantification of said material is produced and based on this the central government will give the matching incentive to compensate the losses if any.

Another big move by the government of India is the announcement of the setting up of three major bulk drug parks in the country with an outlay of Rs 1000 crore each for their development. Already foundations have been laid in Himachal Pradesh, Uttar Pradesh and the land acquisition process is under way for the bulk drug park in Andhra Pradesh. If the bulk drug parks are developed, the pharma industry will get support in the form of a common effluent treatment plant, continuous energy and power supply, low-cost land availability and adding to it the support of research-based incentives by the government that will revive India's bulk drug sector and help it compete with big international competitors like China in the global markets.

Why was India pushed into the turmoil of excess dependency on China for APIs, what went wrong that led Indian bulk drug companies to close down?

The major reasons that led India to become over-dependent on China were the government's policy decision to revise the pharmaceutical public sector units like IDPL, Hindustan Antibiotics Limited (HAL) and others. In the early 1950s, these PSUs supported by the government were able to meet the domestic API needs of the pharmaceutical sector.

Unfortunately, due to some reason the Government of India revised its PSU policy and both IDPL and HAL closed down and following this, the government also decided to de-revise products like Pen-G and 6-ADA from the public list. I was also one of the people on the review panels of the policy decision. Later the government encouraged the private players to take up the responsibility of producing bulk drugs and invited them with their proposals. A few companies like Torrent Pharma, Themis and Madras Chemicals came forward, The Centre encouraged these companies and after analysing their technologies 3-4 companies with investments of Rs 150-300 crore, were given licenses to produce Penicillin-G and 6-APA bulk drugs which are important in the manufacture of vital antibiotic medicines.

However, after a year or two, these companies reportedly faced intense competition from China. From $20 per kg in the open market, China continuously started reducing the price from $20 to $18 to $15 to $12 and now the APIs from China are sourced at as low as $5-8 per kg. Not able to face such intense international competition, these players again approached the Government of India for help, but the latter could not come to their rescue and they had no other option but to close down their units. That's how our entire industry started sourcing APIs from China, and even today we are relying on China for all our major pharmaceutical needs.

Now as times have changed, India realised its deficiencies and it wants our industry to reduce its dependence on China and has come out with hand-holding schemes like Production Linked Incentives (PLI) schemes, which are great initiatives to help our bulk drug sector become self-sustained to meet our future domestic and also the international needs.

What kind of support do the SMEs in the pharma sector expect from the government?

Small and Medium Enterprises (SMEs) within the pharmaceutical sector have been performing exceptionally well and significantly contributing to India's exports. Regrettably, these SMEs have not been receiving the necessary support from the government. It is indeed paradoxical that the government, while allocating substantial funds for the welfare of the underprivileged, is not extending support to SMEs dedicated to producing high-quality medicines that cater to the healthcare needs of these very citizens.

If the government were to allocate at least 5-10 per cent of the amount it currently directs toward direct welfare programmes for the less fortunate to support SMEs, the Indian pharmaceutical industry could automatically align itself with international standards, matching countries adhering to the Pharmaceutical Inspection Convention (PICS), and also meet the requirements of the new World Health Organisation Good Manufacturing Practice regulations.

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