

## **Pharmexcil's capacity-building programme to bring more awareness on safety and regulatory standards**

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**Despite all hurdles India's exports are growing positively and witnessed a 4.6 per cent growth in the past 5 months period in 2023**

The Pharmaceutical Export Promotion Council of India (Pharmexcil) is conducting regular capacity-building programmes across various leading cities in India with an aim to bring more awareness and share knowledge among the small and medium-scale enterprises in pharma and biotechnology companies pertaining to safety and regulatory standards and helping them to overcome the export-related challenges.

According to Ravi Uday Bhaskar, Director General (DG) of Pharmexcil, the main objective of the capacity building programme is to bring in more awareness on the safety and regulatory standards to be complied with, particularly among the pharma and biotech companies, who are involved in exports.

"In pharma and bioscience-related industries, there is no room for error. These industries have to follow strict and uncompromised regulatory standards in all aspects of their production lines. Unlike earlier, each and every pharma and biotech company should mandatorily follow strict safety and standard regulations and must comply with Current Good Manufacturing Practices (cGMP) by adopting the most advanced and latest trends and techniques. In view of this, the Pharmexcil has decided to conduct capacity-building programs across major 10 cities in India. Already we have conducted

awareness and training programs in Ahmedabad, Kolkatta, Hyderabad, Mumbai, and Chennai for various SME companies,” informed Uday Bhaskar.

As part of the capacity-building programme, the Pharmexcil is inviting lead speakers from USP, CDSCO, and other leading regulatory organisations from across the globe and spreading awareness, and sharing knowledge and data with all the participating companies.

Referring to the recent issue of not of quality Cough Syrup being exported by some Indian companies to the Gambia, which led to falling sick of many children consuming it, following which the United Nations raised its concern and even blacklisted a few Indian companies, the Pharmexcil Director General termed it as the most unfortunate incident ever happened to Indian exporters until now.

“The cough syrup issue has really had a big dent in the brand image of the Indian Pharma sector. All these days we were claimed to be the ‘Global Pharmacy Hub’ and have a good name across the world as the supplier of affordable, quality medicines to the Globe. But this one single incident has definitely raised questions and apprehensions among the world countries about the quality standards and safety and efficacy of our medicines. Therefore, Pharmexcil felt that it is time that we build the capacities of all those SMEs who are in the export business, and by creating awareness, sharing knowledge and expertise, the council is extending a helping hand and doing its bit to see that the Indian pharmaceuticals industry achieve greater growth in the coming days ahead,” observed the DG.

Uday Bhaskar also stressed the need to amend Schedule M and bring it as an Act by passing the law in the parliament. The draft regulations for Schedule-M, have were crafted in 2018. However, even to date, the central government has made it into an Act. “If Schedule M is implemented, we can make sure that each and every pharma and biotech company complies with end-to-end safety regulations. And if this comes into force India will also become an ICH member and our pharma companies will have better access to the global markets,” stressed Bhaskar.

Explaining India's exports and its growth trajectory, Uday Bhaskar said that despite all hurdles India's exports are growing positively and witnessed a 4.6 per cent growth in the past 5 months period in 2023. He said that the blacklisting of some of the Indian Pharma companies supplying cough syrup by the UN has not had any major impact on India's overall pharma exports.

Referring to India's share of exports globally, Bhaskar said that India is still a major supplier of good quality and affordable medicines to western countries including the USA and EU. More than 55 percent of India's pharmaceutical exports are going to the Western world.

“No doubt India is the number one exporter of generic formulations in the world, while China is leading in APIs. However, our main concern is that India is still depending on China for its APIs. Even though our government had taken some initiatives to make India self-sufficient in the API segment by implementing the Product Link Incentive scheme, there is still a lot to be done to grow big in the API segment,” felt the Pharmexcil DG, while sharing his views with BioSpectrum on India's API sector.

**Amguthr Raju**