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Regulator wants new GMP vaccine plants

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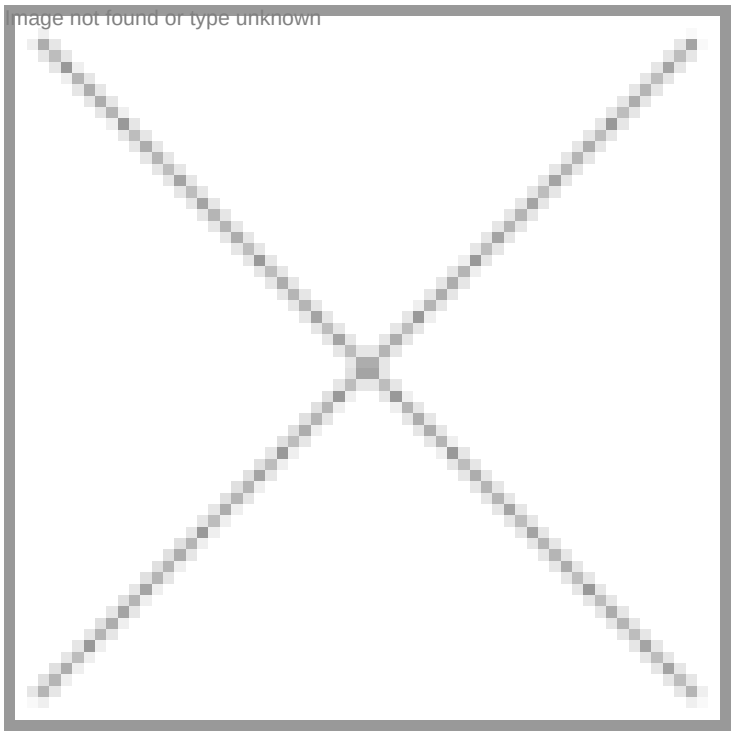

Regulator wants new GMP vaccine plants

-Dr Surinder Singh, Drug Controller General of India.

India's vaccine industry has been facing a stormy weather due to the World Health Organization's (WHO) decision to go slow on products made in the country. This was because the government laboratories on which the Indian regulator, the Drug Controller General of India (DCGI), relied for tests had outdated facilities and were forced to shut down over quality issues. The three vaccine manufacturing plants in the public sector are located at the Central Research Institute (CRI), Kasauli, Himachal Pradesh, BIBCOL, Bulandshahr, Uttar Pradesh, and King's Institute, Chennai.

The vaccine industry's cries over this "quality" issue threatening their export orders have been finally heard. The regulator has recommended a quick remedial action which can help remove the dark clouds hanging over the Rs 1,900 crore Indian vaccine industry.

The regulator has recommended to the Ministry of Health to set up new GMP (Good Manufacturing Practices) compliant, global standards manufacturing plants urgently to resume production of vaccines in the government sector in the country.

Excerpts from a media interaction with the Drug Controller General of India, Dr Surinder Singh, during the 6th Pharma Summit, organized by the Confederation of Indian Industry (CII) in Mumbai in mid-September

Is the government going to modernize the three vaccine plants which have been shut down over quality issues?

We have submitted a report to the Ministry of Health on this issue and it has concluded that the three facilities did not follow GMP and they cannot be modernized and made GMP compliant because these are very old institutions. Some of these institutions were set up over 100 years ago.

So what is the way out?

We have recommended that the essential vaccines which were made in these plants should continue to be manufactured in the country but not in these facilities but in new state-of the-art GMP-compliant facilities.

What happens to the highly qualified technical personnel who were employed in the shut down facilities?

We have to make the best use of the trained human resources available in the existing facilities. We have recommended granting approval to start the production of some important products like the yellow fever vaccine. Rabies tissue culture vaccines, seasonal influenza vaccine (because of reasons pertaining to national security) and typhoid vaccines. The new facilities could also increase the production of anti-serum, which is in short supply now.

Are you going to increase the number of people at these plants?

The Kasauli institution is looking at increasing the technical personnel from 40 to 150. The number could even go up to 200. This is because the country will require about 5,500 batches of these essential vaccines to be made here in a year.

Will there be a shortage of vaccines in the country?

Every year the country makes vaccines worth Rs 1,900 crore. Out of this, the domestic sales figure is only about Rs 400 crore and the remaining Rs 1,500 crore is exported. Every third child in the world is immunized with measles vaccine made in India. Around 70 percent of the global supplies of this vaccine are from India. In fact, India had exported about 80 million doses of measles vaccine to Pakistan recently. There is no shortage of vaccine for the public health system in the country. There could, however, be some issues relating to timely procurement.

Vaccine industry has been complaining about the low prices given to them during procurement. What is the reality?

Pricing is not at all an issue. For example, an institute with the best GMP facilities manufacturing BCG vaccines would export it at a price of Rs 40 to foreign countries whereas to the Government of India it will be sold at a price of Rs 17.

Is the country improving the regulatory standards?

This is something we are working on. We are at present collaborating with the WHO for training activities and with the USFDA and Health Canada for other aspects. Vaccine manufacturers can now submit their revamp plans electronically. We are also introducing various e-Governance measures to bring reliability, accountability and adherence to timelines. Proposed initiatives include setting up LAN/WAN connectivity of CDSCO campus, online submission of all forms, digitalized interactive portal, digitalization of records and online approvals with digital sign.