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DCGI: Allegations of fake Indian drugs baseless

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The public information cell of the Drugs Controller General of India has issued a statement contradicting a New York Times report that claimed that 'India-made drugs trigger safety concerns in the US'.

DCGI's statement said that the report made some "baseless, irresponsible and malicious" claims by stating that WHO estimates that one in five drugs made in India is a fake.

The report further added that WHO had clarified as recently as on August 31, 2012 that there was no such study carried out by the WHO. "They have also regretted that occasionally some individuals in the media and the organizations use WHO references incorrectly and even irresponsibly," the release said.

The report added that a section of the print media - Indian as well as foreign - has been publishing "factually incorrect and largely unsubstantiated" news "to malign the well-earned reputation of the Indian pharmaceutical industry".

India exports around $15 billion of pharma products, including vaccines to most of the countries in the world. There are about 360 USFDA-approved drug manufacturing units in the country. There are also over 150 European Directorate for the Quality of Medicines (EDQM)-approved drug manufacturing units. As recently as 2013, the WHO has declared the Indian national regulatory authority functional for vaccines against stringent international parameters.

The release said harmonization of regulatory standards has not yet been achieved even among the three major regions - North America, Europe and Japan. A product from India complying with the US standards would still have to comply with the regulatory requirements of Japan if it has to be exported to Japan. India has its own law governing the regulatory norms and standards. Manufacturers have to conform to these norms and standards. However, any Indian pharmaceutical product entering the US market complies with the US standards.

It added that Indian laws and India's robust regulatory framework ensure high standards of quality, safety and efficacy of drugs manufactured in the country.