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Health ministry junks media reports on DCGI, says country being maligned

06 March 2014 | News | By Rahul Koul Koul

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As per the health ministry, the intention appears to be to malign the well-earned reputation of the Indian national regulatory authority i.e. the office of the Drugs Controller General (India) as well as the quality of drugs manufactured by the Indian pharmaceutical industry.

Refering to On 30 January 2014, Business Standard interview of Dr. G N Singh, DCG (I) published on January 30, 2014, with the caption "If I follow US standards, I will have to shut almost all drug facilities", the health ministry termed it as an attempt to sensationalize rhe issue. The context, content and the manner in which the report has been printed appear to have completely distorted the factual statements made by the DCG (I) to make the news item highly sensational. There are adequate provisions under the Drugs and Cosmetics Act 1940 and Rules made there under for ensuring the quality, safety and efficacy of drugs manufactured in India for marketing. In fact Indian drug products are accepted in more than 205 countries which include both developed and developing countries.

The health ministry goes on to refer to a report by on The Times of India, Delhi edition on February 16, 2014 that carried an article reprinted from the New York Times, authored by Gardiner Harris, with the caption "India-made drugs trigger safety concerns in US". The article quotes the statement attributed to Dr GN Singh which had appeared in Business Standard. Harris has, however, gone further to make some baseless, irresponsible and malicious claims by stating that "WHO estimates that 1 in 5 drugs made in India is a fake". However, the fact is that the WHO had clarified as recently as on August 31 2012 that there was no such study carried out by the WHO. WHO has also "regretted that occasionally some individuals in the media and the organizations use WHO references incorrectly and even irresponsibly."

It again mentions a news item that appeared in The Economic Times of February 26, 2014 under the caption "India's Drug

Regulator Seen as Corrupt: Bate". The ministry's statement points out that in the article one Roger Bate of Washington DC think tank, the American Enterprise Institute has been quoted to have stated that "Indian companies are perfectly capable of manufacturing high quality drugs. However, there is a feeling among patients and physicians in the US that the Indian regulator is not monitoring properly. Indian drug regulator is seen as corrupt and colliding with pharma companies. That is damaging India's business in the US." Bate also cited last year's Parliamentary Standing Committee report which had found deficiencies in the drug regulatory system.

The damaging accusations and allegations made by Bate are a direct assault on the integrity of the Drug Regulatory Office of India. The report seems to have been made with an intention to malign the image and damage the reputation of the highest drug regulatory body in the country. The newspaper, on its part, has not taken due care of seeking the version of the government or the regulator before printing such sensational comments by Bate. The statements made by Bate are largely based on his perceptions. As regards the Parliamentary Standing Committee report, it is mentioned that it is a regular feature in any democracy for Legislative Committees to scrutinise the functioning of all Government departments and make recommendations to bring about improvement in their functioning. It is no different in India.

"The fact of the matter is that the office of Drugs Controller General (India) was inspected by an international team of WHO in 2013 and WHO has declared the Indian national regulatory authority functional for vaccines against stringent international parameters. The Indian pharmaceutical industry has also created an enviable niche in the World market for itself. India exports around US$15 billion of pharma products including vaccines to most of the countries in the world. There are about 360 US FDA approved drug manufacturing units in the country. There are also over 150 EDQM approved drug manufacturing units," health ministry release said.

Terming the regulatory issues as global and not only India specific, health ministry goes on to say, "It is absolutely imperative to mention that harmonization of regulatory standards has not yet been achieved even among the three major regions, viz. 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."

The ministry further reiterated that the Indian laws and India's robust regulatory framework ensures the high standards of quality, safety and efficacy of drugs manufactured in the country. The allegations made in these news items are appears to be baseless and solely printed with the intension of harming the reputation of the Indian national regulatory authority as well as Indian drug industry.