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Indian government backs generic drug industry

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A fortnight after Ranbaxy's $500 million settlement with the US Department of Justice after it pleaded guilty for civil and criminal charges pertaining to irregularities in in its data integrity and manufacturing processes, the Government of India has came forth with an assurance about the drugs being manufactured in India being subject to scrutiny by various agencies.

It says," There have been extensive media reporting in the print as well as electronic about on the quality of drugs (pharmaceutical products like APIs and formulations) manufactured in India for exports. Some isolated reports have also been received about export of spurious / counterfeit drugs attributed to some source in India. There are reasons to believe that vested interests are raking up isolated issues reported regarding technical deficiencies on manufacturing and GMP. India is enjoying a unique position of low cost manufacturing and highest quality medicine, best of both the worlds. (The) Government has strong reason to believe that some of the spurious drugs detected in the international markets, alleged to be exported from India, are desperate attempts by other countries getting affected by the strength of Indian pharma industry."

Several newspaper reports of hospitals issuing directives to stop issuing Ranbaxy medication have also led to serious doubts about the quality of medicines. The press note says that while the Pharmaceutical sector is a highly regulated one and the exports are heavily guided by various regulatory regimes of the importing countries, there is also a requirement for continuous monitoring of quality related aspects including complaints of sub-standard / falsified drugs from various countries. All the concerned organizations in the government are constantly interacting to ensure that India's image as a safe exporter is protected from all angles. Government and the industry is already working on a 'trace and track' mechanism which would enable monitoring of the supply chain possible at all the three levels viz. Tertiary, Secondary & Primary.

Pharmexcil, the industry body for pharma exports states that, India had, as on 30th December 2012 over 3000 Drug master filings (DMF's) with USA amounting to a almost 40% of the total DMF's filed With USFDA. These are filed by over 233 different companies from India. During the year 2012 USFDA has granted 476 ANDAS and India has 178 market authorizations of them i.e. amounting to 37.4% of the total. As on 30th Dec 2012 over 2275 ANDA's (Abbreviated new drug

application)(Generics) are approved by USFDA covering over 31 different companies. There are over 550 manufacturing sites registered with USFDA out of Which 323 sites are approved by USFDA as on 31st March 2013. 30 companies have over 902 CEP's approved by EDQM, which is more than 25% of the total CEP's approved by EDQM globally. 27% of the formulations are exported to USA and India has a share of 15% of US generics by way of volume.

The government reiterated its stand of India being a low cost quality exporter of drugs by saying that "There are more than 350 manufacturing sites endorsed by EU for their GMP in India as on 30th April 2013. All the facts quoted above speak about India's ability to harness large talent pool to produce quality pharmaceuticals - second to none in quality and that too at the most competitive prices.(The figures) indicate the strong presence of Indian industry in the US and the reports of US FDA penalizing Indian companies are only a small aberration."

India is currently 4th in the world in terms of production volumes while it is 13th in domestic consumption. Over 55% exports of India are to highly regulated markets.USA is the largest exports destination followed by UK. India is also the largest exporter of formulations in terms of volume with 14% market share and 12th in terms of export value of bulk actives and dosage forms.