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Drug counterfeiting is a criminal act: PSM report

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Only few adhere to manufacturing standards: PSM Report

According to a report by the Partnership for Safe Medicine (PSM) India on "Patient Safety and Drug Detection Technology" released on 15th February 2013 at New Delhi by Mr Keshav Desiraju, secretary, ministry of health and family welfare, India has more than 10,000 manufacturers of pharmaceutical products, but very few qualify the standards of Good Manufacturing Practices (GMP).

Speaking at open house consultations on "Accessibility to quality medicines in the supply chain", where the report was released, Mr Bejon Misra, founder, PSM India said, "The real challenge is to change the mind-set of the small scale manufacturing units and make them understand that manufacturing good quality medicines will fetch profit and bring good return on investments rather than perpetually living under the threat of the law enforcers or in the mercy of the unscrupulous traders/retailers."

Mr Desiraju outlined that few manufactures think that it is not their concern and regulators only have the responsibility to catch the culprits. "But that must not be the case. Counterfeiting is a criminal act and should be treated like one. There has to be a common goal in ensuring the safe and quality medicines and we are all part of this society. We are moving into the direction of enforcing technology as mandatory for tracking and tracing," he told BioSpectrum.

The report of the International Workshop held in India in September 2012 had emphasized that 2D bar coding and a unique universal product identification system should become mandatory under the provisions of the existing Indian Drugs and Cosmetics Act. There are also no provisions relating to the same for imported drugs, which should also get included into the existing law. To facilitate efficient drug recalls, global standards and best regulatory practices, India must adopt a sound track and trace system across the supply chain. This will not only provide safety and quality medicines to the patients but also improve tax collection from pharmaceutical products and reduce drastically not-of-standards or spurious medicines from the supply chain.

The report mentioned that government of India should also expedite the process of implementation of effective 'track and trace' systems already made mandatory for all products meant for exports and domestic products which are under price control. The technology to be selected should be vendor neutral, based on best global standards, simple in implementation and affordable, especially for the small scale manufacturers.

The PSM report recommended that adequate reference standards need to be made available to laboratories to keep up with new types of formulations and Indian regulatory officials should be invited as observers in the inspections of manufacturing sites by European Union, US FDA and regulatory agencies of other countries.