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India takes steps to ban unsafe drugs

18 January 2013 | News

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As a first step to prevent the misuse of those drugs banned in abroad from being sold freely in the country, Indian drug regulator has directed all companies to conduct clinical trials of generic medicine products and seek the national drug regulatory approval within 18 months.

So far, hundreds of fixed dose compounds (FDCs) were marketed all over India by just registering with the state-level drug licensing agencies bypassing the national drug regulator, the drug controller general of India (DGCI). The trigger for this regulatory action, which was initiated on January 15,2013, is the recent development related to the unfettered sale of a banned anti-depressant drug compound, flupenthixol+melitrcen, with the original trade name of Deanxit.

More than a dozen Indian generics manufacturer sell this drug in India even though Deanxit made by Lundbeck, a Danish company. The Danish regulator banned the sale of this drug there because of its dangerous side effects such as abnormal heart rhythms. Surprisingly, the Danish regulator allowed manufacture and export of Deanxit to other countries and the Danish company sells it in India.

On January 10, 2013, the DCGI, Dr GN Singh took the first step to ensure safety by directing all manufacturers of this drug in the country to submit clinical data about its safety within six months. The drug has been in use since 1998 without conducting clinical trials about its safety and efficacy. If safety data of flupenthixol+melitracen is not provided within six months, its use will be banned in the country, the regulator has warned.

Many prominent companies such as Sun Pharma, Intas, Unichem, Esma and low-profile ones such as Psycorem, Molekule, Aster, Archicare, Genesis, Daksh, Unimarck, and Amico sell this drug in the country.
This directive by the DCGI is an extension of the case. Based on the Deanxit example, the regulator has asked manufacturers and marketers of all FDCs to submit safety data within 18 months. Analysts estimate that there are more than 300 drugs which have got into the Indian market in the last two decades without generating any clinical trial data.

A parliamentary committee which studied the issue in mid-2012 had highlighted the loopholes that exist in the drug regulatory system that allowed the proliferation of dangerous drugs banned abroad being freely made available in the country.

In 2007, the national drug regulator had banned 294 drugs which got into the country through the state-level licensing route without safety and efficacy reports. However, these drugs continue to be sold to patients, based on a stay order issued by the regional High Court in Chennai, Tamil Nadu state. Till this case is disposed off by the court, the 294 "banned" drugs will continue to flood the markets.

In further tightening the rules, the national regulator has instructed that any new drug can be licensed by state-level agencies only after the approval of DCGI is obtained. Analysts welcome this move which seeks to enhance patient safety and crack down on manufacture of substandard and unsafe drugs in the country.