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Maharashtra FDA begins probe into sale of counterfeit version of cancer drug BiCNU by Taj Pharma

Laxmi Yadav, Mumbai, Saturday, June 04, 2016, 08:00 Hrs [IST]

The Maharashtra FDA in coordination with the DCGI office has initiated investigation into the alleged sale of counterfeit version of Emcure Pharmaceuticals' chemotherapy agent BiCNU (Carmustine for injection) by Mumbai based Taj Pharmaceuticals violating Drugs & Cosmetics Act, 1940 and Rules made thereunder.

The probe was launched by the FDA following complaints by IPR committee of IDMA in this regard. Emcure had approached IDMA IPR committee seeking assistance to take action against Taj Pharma for selling counterfeit version of cancer and brain tumour drug Carmustine in global market thereby jeopardizing public health, informed Dr Gopakumar Nair, chairperson of IDMA IPR committee.

Emcure also had filed a case against Taj Pharma in Bombay High Court in April 2016 for counterfeiting, exporting and internationally marketing Emcure's Carmustine brand by name BiCNU.

Advocate Birendra Saraf appearing for Emure told the High Court that the drug is a sensitive product that requires to be maintained and stored at specified temperatures and needs very careful handling. It is administered under close monitoring. Its misuse is said to be fatal. The counterfeit injection BiCNU was found to be fraudulently sold by Taj Pharmaceuticals Ltd., Mumbai and Taj Accura Pharmaceuticals Ltd., Ireland to Israel based Raz Pharmaceuticals Ltd by showing that it is the original injection BiCNU which is manufactured by Emcure, he said.

The High Court, hearing the case, found no merit in the documents submitted by Taj Pharma in support of sale and manufacturing of BiCNU and directed a court receiver to attach Taj Pharma's assets. To rein in property seizure, two of the company's directors gave an undertaking in the High Court that they would not export any pharmaceutical products, till the court decides in the matter.

The matter came up once again on May 3rd and 4th, 2016, in the High Court of Bombay, consequent to Taj Pharma issuing misleading press release about the order of April 21, 2016. The High Court passed severe strictures against the conduct of Taj Pharma amounting to contempt of court.

On November 20, 2012, Emcure and Bristol-Myers Squibb Company executed an asset purchase and sale agreement and Emcure acquired the technology, trademarks and other worldwide rights etc. of Carmustine being manufactured and sold by BMS. Emcure also acquired the trademark "BiCNU" under which Carmustine was being sold by BMS worldwide. From January 2013, Emcure started manufacturing and exporting of BiCNU in various countries such as United States of America, Israel, United Kingdom and other European countries. In some of the countries, BiCNU is distributed/marketed by affiliates and/or subsidiaries of Emcure under strict supervision. However, in India, it is sold as "Consium". It is in this context, that the alleged counterfeiting by Taj Pharma attracts disturbing attention.

Emcure sells/exports its products in Israel through its subsidiary Emcure Pharma UK as stated above.

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