Uttarakhand Drug Controller Bans Manufacture & Sale Of All FDCs Approved By State FDA Following CDSCO Crackdown (26-03-2018)

Mumbai, 26 March 2018: The Uttarakhand Drugs Controller has suspended manufacture, sale or distribution of fixed dose combination (FDC) drugs approved by it following the recent crackdown by CDSCO on the premises of two drug manufacturers-- Ambic Aayurchem in Roorkee and Mascot Healthcare in Haridwar which were involved in manufacturing of FDC of metformin HCL and teneligliptin hydrobromide hydrate, teneligliptin and pioglitazone HCL, pioglitazone, itraconazole and terbinafine HCL without approval from Drugs Controller General of India (DCGI).

Acting on an information that certain FDCs falling under the new drug category of Drugs and Cosmetics Rules, 1945 were being manufactured by Ambic Aayurchem and Mascot Healthcare without DCGI approval, CDSCO along with state drug authority and local police had raided the premises of both companies on March 15- 16, 2018.

However these FDCs are licensed by the state licensing authority.

During the search, the team of CDSCO and state FDA officials found around 10,000 tablets of Betawin- IT (FDC of itraconazole USP (100 mg) + terbinafine HCL BP (250 mg)) worth Rs.3 lakh on the premises of Mascot. This product is being marketed by Wockhardt Ltd, Mumbai, Medley Pharmaceuticals Ltd, Mumbai, Galpha Laboratorie, Nectar Biopharma, Biological E Ltd, Knoll Healthcare, May and Baker Pharma etc. 73 out of 118 products of Mascot were found unapproved by the DCGI. These products are being marketed by Macleods Pharma, Mumbai, Medley Pharmaceuticals, Geno Pharmaceuticals, Goa, Wanbury Ltd, Mumbai, Dr Morepenm Delhi, Wallace Pharma Mumbai etc.

At the premises of Ambic Aayurchem, the team had found one lakh tablets of Tennyl Trio (FDC of metformin hydrochloride IP (500mg) + teneligliptin hydrobromide hydrate equivalent to teneligliptin (20mg)+ pioglitazone hydrochloride equivalent to pioglitazone (15 mg)).

The product is marketed by Johnlee Pharmaceuticals, Mumbai, Alde Medi Impex Ltd, New Delhi, Vasolif Healthcare, Chandigarh. Ambic was also involved in manufacturing of five new FDCs which were unapproved by DCGI. It was also involved in manufacturing of nateflinide, metformin HCL and pioglitazone being marketed by United Pharmatech, Mumbai.

Following the raids, the state Drugs Controller formed a two-member committee comprising Gaurav Singh, senior drugs inspector, Haridwar and Neeraj Kumar, drugs inspector, Haridwar to examine each and every product approval given to the manufacturers in the state and to submit report on FDCs which have not been approved by DCGI.

A period of three months have been given to the committee to examine and submit the report along with suggestions, if any.

Uttarakhand Drugs Regulator in a letter stated that the issue of grant of approval of FDCs is being probed by the panel, until further orders of state drugs controller, the manufacturing of FDCs approved by Uttarakhand FDA is put on suspension.

In this connection it is pertinent to mention that combination of two or more drugs i.e. FDC combined for the first time fall under the definition of new drug. The requirements for import, manufacture of new drugs including FDCs were introduced to Drugs and Cosmetics Rules, 1945. Permission from the office of DCGI is required before these are licensed by state licensing authorities (SLAs) for manufacture, sale in the country. The parliamentary standing committee (PSC) on health and family welfare in the 59th report on the functioning of CDSCO observed that some of the state licensing authorities have issued manufacturing licenses for a very large of FDCs without prior clearance from CDSCO. This has resulted in the availability of many FDCs in the market which have not been listed for efficacy and safety. This can put patients at risk.

From time to time, the ministry of health and family welfare has issued directions to the state governments under Section 33 P of Drugs and Cosmetics Act to instruct their drugs licensing authorities to refrain from granting licenses for manufacturing of new drugs and FDC. This matter was also discussed on several times in Drugs Consultative Committee meetings.