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EU's latest moves on counterfeit drugs cause fresh concerns to Indian pharma

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The recent moves by the developed countries, especially the European Union, on the counterfeit medicines issue have caused fresh worries among the Indian generic exporters, prompting them to take recourse with the authorities for renewed efforts including international intervention along with other developing countries.

While the European Commission is proposing a new directive against counterfeit medicines, the Council of Europe has prepared a convention on counterfeiting of medical products and similar crimes involving threats to the public health. Both the moves have caused ample worries for the Indian industries as they feel that it was in the same line of the IMPACT attempt in the WHO some time back.

The industry associations back home have called upon the government to take up the matter and at all possible levels to protect the interest of the domestic industry. "We have urged the government to take it up at political, diplomatic and bureaucratic levels to drive the point and ensure the availability of quality medicines at affordable price by developing countries," according to SME Pharma Industries Confederation vice-chairman Lalit Jain.

According to the draft convention being finalized by the Council of Europe this week, the manufacturing of counterfeit medicine has to be sanctioned. According to Article 6, 'Each party shall take the necessary legislative and other measures to establish as offences under its domestic law when committed intentionally, the supplying or the offering to supply including brokering, the trafficking, including keeping in stock, import and export of counterfeit medical products, active substances, excipients, parts, materials and accessories'. And a counterfeit medical product is defined as 'a product with a false representation of its identity and/or source'.

However, the Indian industry has slammed it as another tactic to assault the generic industry. "These are moves to promote IMPACT type legislation and EU is already doing this through their falsified medicines directive. Then what will be given to developing countries is legislation similar to that of EU i.e. on falsified medicines. This new EU - Directive has coined term falsified medical products instead of counterfeit, which developing countries have opposed successfully in WHO," Jain said in a letter sent to the Pharma secretary listing the harmful clauses in the proposed legislations by the European countries.

At its second and final meeting on September 1 to 4, 2009, an ad hoc committee on counterfeiting of medical products and similar crimes has agreed on a draft text of the Convention. This text has been transmitted to the European Committee on Crime

Problems (CDPC) for finalisation at the Committee's plenary meeting being held this week, it is learnt.