



## PHARMACEUTICALS EXPORT PROMOTION COUNCIL

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Date : 27-01-2010

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### **Swedish proposal for linking marketing approval of drugs with environmental norms may affect Indian industry**

Wednesday, January 27, 2010 08:00 IST

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<http://www.pharmabiz.com/article/detnews.asp?articleid=53712&sectionid=>

In what can cause an adverse impact on the Indian pharma industry, the Swedish Medical Products Agency has proposed a legislation by the European Union for linking of approval of medicines with the environmental risk assessment of the production facilities where the outsourcing of drug manufacturing takes place.

The agency has put forward the proposal in the wake of increasing outsourcing of manufacturing-related process by EU pharma firms to the developing countries where it feels that norms on environmental pollution were not stringent. The immediate provocation for the move was the recent studies held by Swedish researchers in India, according to the sources.

The study held between 2006 and 2007 in 90 companies, mainly into API manufacturing units, in and around Hyderabad and funded by the Swedish International Development Cooperation Agency had found that emissions from these facilities were at a level that could seriously affect human and animal health, as well as the environment. Researchers sampled the waste exiting the plants and found drugs including the antibiotic ciprofloxacin, at concentrations of up to 31,000 micrograms per litre, and the antihistamine cetirizine, at up to 1,400 micrograms per litre. The study team estimated that the amount of ciprofloxacin entering the river from the plant could amount to up to 45 kilograms a day – the equivalent of 45,000 daily doses.

In this background, the Swedish agency has suggested linking of drug approval to environmental risk assessment through amendment in EU legislation concerning the pharmaceutical industry. If there is any risk of negative environmental effect during assessment, the marketing approval for the drug should be denied, according to the proposal. The 'discharge of substances from pharmaceutical production in the third world is of sincere concern', the agency says in the note. It also suggests change in the regulations on good manufacturing practices to make environmental certification mandatory for API units.

“A significant part of the current manufacture and production of raw materials or intermediate products takes place in low-cost countries and many large companies are planning to place even more of their production there. National legislation is insufficient and these measures are better met with harmonised EU legislation, since level of requirements also may affect conditions outside the EU,” the MPA says.

The agency has submitted the report with these recommendations to the government and it would be placed for public consultation at national level. The government, then, will approach the European Commission for necessary amendment in the EU legislations. If pushed to the logical end, it will add heat on the Indian industry which is emerging as the choicest destination for outsourcing. Besides, the small and medium scale companies are already finding it tough to implement all the existing norms on environmental pollution.