

Pharmexcil suggests DGFT to provide sops to exporters to develop norms for non-infringing process for APIs

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The Pharmaceutical Exports Promotion Council (Pharmexcil) has suggested to the director general of foreign trade (DGFT) to provide incentives to the pharma exporters to develop adhoc norms for non-infringing process for bulk drugs to increase the export of pharmaceutical products in the regulated markets. The suggestion was put forth by Pharmexcil at a high level meeting held on September 1.

Dr P V Appaji, executive director, Pharmexcil informed that they have impressed upon the demands of the exporters that provision in the FTP should be given to recognize the companies exporting to regulated markets and holding patents for their products to give relaxation in advance license norms.

According to Dr Gopakumar Nair, advisor, Pharmexcil, the main aim behind Pharmexcil to urge DGFT for developing norms for non- infringing process patent for bulk drugs is to encourage and develop export of APIs and dosage forms through non-infringing processes. He pointed out that even though India has achieved technological maturity in pharmaceuticals, it has yet to go a long way ahead when it comes to drug discovery and research. In the meantime, having definite norms for non-infringing process patent for bulk drugs will not only increase the pace of development of R&D in Indian pharma companies, but also will increase the export opportunity for Indian bulk drugs producers in the regulated market.

In pharma industry, prior approval of the regulatory authorities in countries like US, Europe, Australia and South Africa, is required prior to the launch of the product. In such regulated markets the quality needs to be maintained as per their standard and the process should not infringe the existing process patents in those countries, even after the new chemical entity (NCE) patents expire.

In this process, pharma companies follow different processes and purification methods which may lead to lower yield and consumption of more raw materials and solvents for manufacturing generic drugs without infringement of process of innovator. Various steps are involved in manufacture of drugs to meet quality requirements of the regulatory authorities and to ensure compliance in terms of impurity profile, purity levels as well as to ensure that the processes adopted through in-house process development, do not infringe any other process patents in the regulated markets.

To comply with these requirements manufacturing process followed is often different from the already patented one. It is, therefore, suggested by Pharmexcil that a provision in the EXIM policy should be given to recognise the companies exporting to regulated countries and holding process patents for their products by giving relaxation in advance license norms. Value addition may also be considered for fixing the norms for such products in similar proportion.