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Pharma cos fear new EU quality rule

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First, the tender-based system in certain key European markets eroded margins of key Indian pharmaceutical firms. Now more trouble from Europe seems to be on the way in the form of a directive of the Falsified Medicines Act.

Come July 2013, the European Union (EU) will insist that each and every pharma export consignment be accompanied by a letter from a competent authority in the country concerned certifying that the products were manufactured to meet European quality standards.

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"The letter (requirement) was to come into force from April 2013. Now we are told it would happen from July 2013. We are awaiting further clarity on the issue," said a senior employee of a generic pharma major.

Implications abound for active pharma ingredients (APIs). India currently exports about $1 billion worth of APIs annually to Europe; and 220-250 companies depend on the EU market for a significant portion of their revenues.

The government is said to be working on naming a competent authority that can issue the certificate. "There are indications that the Drugs Controller General of India (DCGI) would be the competent authority. We are hopeful of handling it appropriately," an official source said.

According to sources, India has an option of getting recognised as an equivalent country to the EU which would obviate the need for the certificate.

But the industry is not pleased. For, the process of obtaining a letter for every export consignment would be time consuming.

"We still don't know if the required letters would be issued as per export schedules. However, going by the past experience, we anticipate some delays which, in turn, could affect the export revenues at least initially, till a proper system is in place which will likely take some months. An option is to plan well and factor in the delays," said a CEO of a pharma major.

According to industry sources, the European Fine Chemicals Group (EFCG), an industry group in the EU, is said to be pressing hard for clamping down on substandard imports, particularly from China and India.

"The European industry group alleges that Asian companies, particularly those in China and India, have been exporting low-quality products. Its members have been on inspection visits of the European regulator to manufacturing facilities in Asia," said an industry source.

The new directive requires neither mandatory inspection of all global API manufacturers for good manufacturing practices (GMP) compliance nor the traceability of the manufacturing sites that produce APIs sold in the EU. Instead, the responsibility to verify compliance remains with either the authorisation holders auditing suppliers to the EU or a third party.

The competent authority to be named by the government would thus be the authorisation holder.

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