

Karnataka DC cautions SMEs over new regulatory challenges in global markets

Saturday, November 20, 2010 08:00 IST

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Changing dynamics in the global pharma scenario are expected to post serious challenges to the Indian small & medium enterprises players in future. With many countries coming up with new guidelines to make registration procedures tougher and thereby creating entry barriers, the going could expect to get tougher.

The new stringent regulatory norms and high quality standards and increased transparency & accessibility of information on web on real time basis adds new dimension and only points to the fact that the era of simple registrations would soon come to an end, said Dr Jagashetty, Karnataka Drugs Controller.

India has a significant presence in the international market and therefore companies need to cope up with ever increasing regulatory issues. Large pharma firms that already have presence in the highly regulatory markets of Europe, USA and Japan are adjusting to new regime, but the same cannot be said about the SME sector.

Delivering the key note address at the Pharmexcil seminar on 'Export Promotion and Patent Awareness', he said, "Now is right time for SMEs to gear up for the emerging challenges and manage their resources well to ensure they meet the regulatory requirements. This, besides increasing their capability would also help them to tide over the fresh challenges thereby ensuring that they are not left behind."

Besides pharma sector the onus is also on pharmacy institutes to train the technical manpower on par with the global needs as this would be the only way to keep pace with the rapid developments taking place internationally, he opined. Further, he pointed out, "we as a country need to consider the Patent regime and various associated issues with sufficient seriousness to become globally competitive. Currently, the awareness regarding patent and its importance is rather low and there is tremendous amount of work that needs to be done".

Indian pharma has devised two strategies: The first being inking strategic alliances with large generic companies and the second to enter into contract manufacturing agreements with innovator companies. These strategies have been adapted by few companies, the success and failure of it or impact of such strategies on the future of Indian pharma industry as a whole or on a country like India is yet to be assessed completely and is yet to be evaluated conclusively. There are many more strategies or paths adapted by small, medium and large Indian pharma companies to overcome the issues posed by the current Indian Patent System, global economies, research/innovation challenges and various other aspects like price control etc.

Globally Indian pharma is 4th largest in volume terms and 13th in value. It is also home to the highest number of US FDA plants and large pool of scientific skills making companies much-sought-after in CRAMS (contract research & manufacture services). The sector's domestic performance is a parameter of regulatory adherence and patent filing. Now the doors are open to expand business globally with a pipeline of products. Indian pharma is also known for its technical expertise in systematic dossier filings for exports.

Outlining the key challenges, the Karnataka Drugs Controller stated that it was essential for pharma companies to maintain the pace of new drug pipeline, ensure economies-of-scale, increase intellectual property (IP) competence, enhance scientific pool and strengthen regulatory expertise. These initiatives would ensure faster turnaround and make India a potentially strong global pharma hub.