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# Indian drug cos need to focus on niche segments in US generic market: Pharmexcil Study

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The Indian pharma companies should focus more on complex chemistry, biotech-based medicines and advance formulations to tap the lucrative US generic market in future, suggests a study conducted by Pharmaceuticals Exports Promotion Council (Pharmexcil) – the apex body governing pharma exports under the Union Ministry of Commerce.

The study - Presence of Indian pharmaceutical industries in US market: An empirical analysis - conducted by Pharmexcil reveals that ANDAs from India are confined to small number of highly competitive molecules, the country has evident high hand in Abbreviated New Drug Application (ANDA) and Drug Master File (DMF) Filings.

Majority of the Indian ANDA and DMF filings are on solid dosage formulations especially where a large number of generic products are present in the market. The Indian companies has to focus on fermentation technology based products and niche dosage forms like injectables, new drug delivery systems and dermal products for ANDA and DMF filings to optimise the market potential, says the study published of late in Palgrave Macmillan, Journal of Generic Medicine (UK).

“At present, 20 per cent of our export business is from the US. By tapping the potential in these niche segments, we hope that the exports to US will go up by at least five per cent adding another Rs 3000 crore to Rs 4000 crore to our exports,” said Dr P V Appaji, executive director, Pharmexcil. The council has urged the government to support the industry to increase their expertise in fermentation technology and other niche technologies.

He suggested that the formulations manufacturers in the country should identify niche areas where the Indian companies have not filed ANDAs with the US FDA and should leverage the potential.

The US$ 58.5 billion US generics market is India's largest export destination and nearly one fifth of the total exports from the country goes to the US market. India accounts for one out of every four ANDA approvals in the years 2007 and 2008, ranks first in total Type II active DMFs with US FDA and it also received 31 per cent of all tentative approvals till mid December 2008, explains the study. India has a strong vendor base with 3.75 DMFs per molecule and has filed more than 450 different APIs with the US FDA.

The formulation exports from India to top 28 regulated countries surpassed active bulk drug exports in 2008, which shows the apparent shift in credibility and quality

compliance which gives strength to the Indian formulations export business. Providing emphasis to the niche areas and fermentation technology will extend the market potential for Indian companies, suggests the study.

The Pharmexcil team prepared a comprehensive database on DMFs and ANDA or NDA held by Indian companies' as against the Rest of World and the data was analyzed on various parameters like dosage forms, therapeutic categories, and patent & exclusivity protection of the molecules. It is for the first time an apex council conducts such an extensive study and gets passed through the scrutiny of a scientific group, claims Dr Appaji.

The council has prepared an in depth analysis of company-wise and site-wise DMF and ANDA filings database and is ready to share it with the interested individuals in the industry at an affordable price, he added.