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Indian firms overtake US in FDA drug filings

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A significant portion of filings from India has been made since 2008; Dr Reddy's, Aurobindo and Cipla top the list

C.H. Unnikrishnan

Indian drug makers are gearing up for the big opportunity coming up in the world's largest drug market, the US, as patents for several widely prescribed drugs are set to expire in the next few of years.

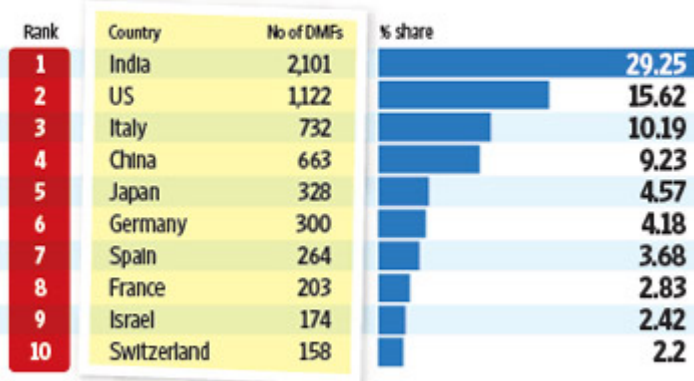
They have filed the maximum number of drug master files or DMFs, accounting for 29.25% of the total 7,183 such filings with the US Food and Drug Administration (FDA) as on September 2009, almost double the filings by local companies.

The DMF is the document filed by drug makers to register active pharma ingredients (APIs) or bulk drugs in the US market. APIs are raw materials used by drug makers who make these formulations.

An analysis of the US FDA database by India's Pharmaceutical Export Promotion Council (Pharmexcil) shows that the country's companies had filed 2,101 DMFs till September.

SEEKING APPROVAL

Top ten DMF* filers at US FDA.



*Drug master files

Source: Pharmexcil research

Graphic: Ahmed Raza Khan / Mint

US drug makers, which led in registering APIs with the regulator till 2007, have filed 1,122 DMFs since 1998, when the FDA amended its norms and opened up the market for global players. The US now ranks second in the list of top 10 countries that filed maximum number of APIs with the FDA.

The US FDA data shows that a significant portion of these filings from India has been made since 2008 with 136 Indian drug makers filing DMFs with the US regulator for at least 450 drugs, including 10 most prescribed molecules such as metformin, amlodipine, simvastatin, omeprazole among others.

Dr Reddy's Laboratories Ltd, Aurobindo Pharma Ltd and Cipla Ltd topped the list.

Apart from India and the US, Italy, China, Japan, Germany, Spain, France, Israel and Switzerland feature in the list of top 10 countries with maximum number of applications, in that order.

“The key reason for the aggressive filing by Indian companies is their preparation for exploring the

imminent generic boom that is awaited in the world pharmaceutical market in the next two to three years,” P.V. Appaji, executive director, Pharmexcil, said on Tuesday.

Nityananda Reddy, managing director, Aurobindo Pharma, also said there is a “significantly large generic opportunity waiting for Indian companies” for both the API and formulation segments of the world pharmaceutical market.

A US FDA registration for APIs and their manufacturing plants testifies to quality and helps companies register products in other parts of the world.

Domestic pharmaceutical industry bodies such as the Indian Drug Manufacturers Association (IDMA) and the Indian Pharmaceutical Alliance (IPA) estimate that patents for nearly \$60 billion of drugs are set to expire in the next four years across the world, and Indian drug makers are in a position to take a significant share of this market.

Bulk drug exports from India were to the tune of \$8-9 billion in fiscal 2009 and currently account for 40% of the world API market in volume.

Since the registration of APIs is directly linked to the approval of formulations for the retail market by the regulator, almost all DMFs filed by drug makers get approved.

Drug makers normally file API documents after reviewing the status of approvals for generic formulations in the US market.

The FDA inspection follows DMF filings and once the factory is approved, the respective company can start using the API in their formulations as well as exporting the drugs to industry clients in the US.

Dr Reddy’s Lab, the largest DMF filer in the US, had 148 outstanding DMF filings in September 2009. The company did not respond to an email query on its increased focus on the US API market.

IPA secretary general Dilip G. Shah said the filings from India show the quality and capabilities attained by the country as a reliable generic drug source.

Another reason for the significant increase in filings is that the export promotion council assists members in complying with requirements.

“This has helped them make the filings error-free and led to least number of rejections,” Appaji said.