Dr Reddy's eyes biosimilars expansion and rejigs research focus

Dr Reddy's Laboratories is in talks with potential partners to push into regulated markets in the biosimilars segment. But the Indian firm, which claims to have sold about 1.4 million units of its biosimilar products in 12 countries so far, also says that approvals in certain emerging markets for such products are taking significantly longer than expected.

"We are preparing to expand into regulated markets and also talking to potential partners. We have also spoken to regulators. The pathways should become clearer in 2012," Dr Reddy's vice-chairman and CEO, G V Prasad, said at a media event in Hyderabad.

Dr Reddy's, which has seven products in various stages of development, has already launched a number of biosimilars, such as filgrastim, pegfilgrastim, darbepoetin alfa and rituximab, in India and certain emerging markets. Filgrastim and rituximab are marketed in about half a dozen countries each, with approvals pending in three and eight countries respectively.

But Mr Prasad did not provide specifics on pending approvals in emerging markets. "Wherever we've got approvals, we've done well, but approvals are taking much longer than anticipated," he noted.

Biosimilars are seen as an important driver of future growth for the firm, with a scale-up in emerging markets projected between fiscal year 2013 and fiscal year 2017 and increasing traction in regulated markets helped by this. In 2010-11, Dr Reddy's Reditux (rituximab) saw 75% growth in revenues to Rs405 million ($7.7 million) on the Indian market.

R&D shift

Meanwhile, Dr Reddy's is "de-emphasising" its new chemical entity (NCE) R&D efforts in the cardiovascular and diabetes segments, focusing instead on areas such as anti-infectives, inflammation/pain and dermatology.

The company cited as some of the reasons for the shift the huge cost of clinical trials to go to market and the potential challenges in improving the

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current standard of care in the diabetes segment, as well as the difficulty in finding large numbers of patients for trials for cardiovascular drugs.

Dr Reddy's managing director and COO, Satish Reddy, clarified however that the company's DRF 17822 – currently in Phase II and targeted at dyslipidaemia and atherosclerosis – continued to be an "extremely strong" candidate. But, "Outside of these we don't have any programme in this stage," he added.

The company is also developing a clutch of novel differentiated formulations for onychomycosis, psoriasis and migraine, and in the anti-infectives segment. It had earlier said that its hybrid differentiated formulations/NCE strategy was anchored around specialty indications with "feasibility to self-commercialise" and a higher conversion from the preclinical to clinical stage.

"Profitability issues" in Europe

Meanwhile, Mr Reddy also believes that the Indian market, in general, will continue to grow in the 13-16% range over the next few years, though macroeconomic conditions may affect the performance of companies to some extent. Other factors that could impact Indian companies include the rapid expansion of field forces and the shrinkage of products available for launch, he noted.

"All these pressures are beginning to play out and hence the numbers may be slowing down," he told the meeting, adding that segments such as the rural market and tier 2 towns still presented significant expansion opportunities in India.

Mr Prasad also observed that the Indian market and Europe had been a "source of dissatisfaction" and that the company needed to rejuvenate, focus and fix things there. Dr Reddy's had since made "tactical interventions" in India and expects to see results in the future.

The firm's revenues in India increased by 9% to Rs3.5 billion in the second quarter of fiscal year 2012, while the domestic industry grew by 15% for the 12 months ended March 2011.

In Europe, where the firm cited "profitability issues", revenues declined by 10% to Rs2.1 billion in the second quarter, with revenues from Germany down 27% due to the continuing impact of tenders.

anju.ghangurde@informa.com