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PHARMA

Generics and enforcement make an impact

Sector expected to grow at a subdued rate of 12% in 2014

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The pharmaceuticals sector, otherwise known for its undeterred growth, isn't hoping for much in 2014. Faced with increasing enforcements and slowing product approvals in many international markets and regulatory hurdles and pricing pressure in India, the drug manufacturing industry is conservative in its approach and estimate for the year ahead.

Market research agency IMS Health revised down its growth estimates for this year to 10 per cent from 17-18 per cent. "This is mainly due to a downward revision in economic forecasts (gross domestic product and private & government consumption) and lower-than-expected growth in the first half of 2013," said Amit Backliwal, the agency's South Asia general manager.

For 2014, the estimate is 11.6 per cent, as pricing pressures and trade issues continue to act as hurdles.

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In 2013, the sector witnessed some significant developments, including the landmark Supreme Court judgment that refused patent protection for Swiss drug maker Novartis' Glivec cancer medicine . Also, major foreign investments such as Mylan Inc's $1.8-billion acquisition of Strides Arcolab's sterile injectibles facility Agila Specialities secured approvals this year.

The year saw generic drug makers Ranbaxy, Wockhardt and Strides facing strictures from international agencies for failing to meet manufacturing norms and regulations at their plants. Such inspections are likely to increase. Experts say companies need to invest more to ensure compliance and protect exports.

"Increased focus of the US FDA (US Food and Drug Administration) and inadequate appreciation of the fast and frequently changing rules by domestic companies could result in more companies facing sanctions," says Indian Pharmaceutical Alliance Secretary-General D G Shah.

The sector will also have to tighten procedures and compliance for conducting clinical trials in the country, following the Supreme Court's directive asking the government and the regulator to keep stricter vigil on such trials.

Praful Bohra, senior research analyst at Nirmal Bang, says most companies are likely to see a major surge in compliance costs. He adds among the large-caps, Lupin, Sun Pharma, Cipla and Dr Reddy's are expected perform better than others, while Ranbaxy and Wockhardt may continue to face hurdles until they resolve regulatory issues in foreign markets. The margins and profitability of mid- and small-cap companies, along with multinationals such as Abbott and GlaxosmithKline Pharma, are also likely to suffer, mainly due to pricing pressures.

Ranjit Shahani, vice-chairman and managing director, Novartis India, said, "We hope we have a progressive and stable FDI policy, an ecosystem which encourages innovation and some sensibility to move the debate from a nationalistic to a healthcare one."

Some are hopeful and expect growth to bounce back next year, despite the challenges. "The road ahead for the industry looks healthy, given the fact that most major players who have developed quality pipelines specifically for advanced markets such as the US & Europe would continue to witness growth, given approvals and launches. In that sense, the overall equation doesn't change much," said a Lupin spokesperson. He added Lupin, currently one of the fastest growing drug makers, plans to grow secularly across the US, India and Japan and enter new markets in Latin America and some parts of Europe, Russia and China.

Industry.