

THE YEAR IN REVIEW Pharma sector

2013 KEY EVENTS

- Supreme Court dismisses Swiss drug-maker Novartis AG's application seeking a stay on its decision on cancer drug Glivec, a landmark decision
- Drug Pricing Control Order (DPCO-2013) brings 248 essential medicines (including 650 formulations) under price control
- Manufacturing units of some India-based companies, including Ranbaxy, Wockhard and Jubilant, are found lacking in current Good Manufacturing Practices (cGMP)
- Ranbaxy settles civil and criminal charges against it in US for \$500 million, over violating cGMP at two plants
- US-based Mylan's Rs 5168 crore acquisition of Bangalore's Agila Specialities goes through
- Torrent Pharmaceuticals acquires Elder Pharmaceuticals' domestic formulations business in India and Nepal for over Rs 2,000 crore
- Ongoing case on clinical trials sees Supreme Court put Government on watch regarding the approval of 162 drugs
- Swiss drug major Roche in August announces not to pursue patent on breast cancer drug Herceptin, in India
- Adversely impacted by price-control norms and implementation, industry growth drops to about 8 per cent compared to 14 per cent in 2012

2014 WATCH OUT FOR

- Slew of litigation and judgments expected, on pricing issues on drug pricing, patents and clinical trials
- Drug price control expected to keep moderate growth subdued in the beginning months of 2014
- Upward price revision expected on some medicines in line with the Wholesale Price Index, around April
- Industry to sort out stand-off with trade on margins issue. Trade seeks 10 per cent margin for wholesalers and 8 per cent for retailers. DPCO-2013 outlines trade margin of 16 per cent for retailers
- Exports expect shot in the arm as patent expiry wave in US continues, creating demand for branded generics
- Lesser deal flow, say industry representatives; more local consolidation possible

No magic prescription

Legal battles scheduled to roll over into next year; more clarity on clinical trials



P.T. Jyoti Datta
Mumbai, Dec. 26

April marked a crucial month in healthcare, as the Supreme Court (SC) delivered its much-awaited judgment on Novartis AG's blood cancer drug Glivec.

The apex court dismissed Novartis' application to patent its drug, and the judgment was this year's slow-stopper, with global ramifications for patients and the pharmaceutical industry.

In fact, litigation was the common thread this year, across developments affecting the industry — be it price control, clinical trials or patent protection. And many of these legal battles are scheduled to roll over into 2014.

Though domestic and multinational companies saw mixed fortunes at different courts in terms of rulings, the interesting feature this year was that companies fought each other.

So, domestic firm Cipla Ltd fought over liver and kidney cancer drug Sunitinib. But Merck and Co Inc and Sun Pharmaceutical Industries Ltd fought on the same

out in some months, the trade's tug-of-war with companies continues. This year saw industry players come together to address the trademark issue, says D.G. Shah of the Indian Pharmaceutical Alliance, a platform for large local companies.

The roll-out of the new price control regime and its allied issues inhibited performance, and industry growth slipped into single digits, touching a hopeful 9 per cent in November. And 2014 is going to be difficult for the above mentioned reasons, says Shah.

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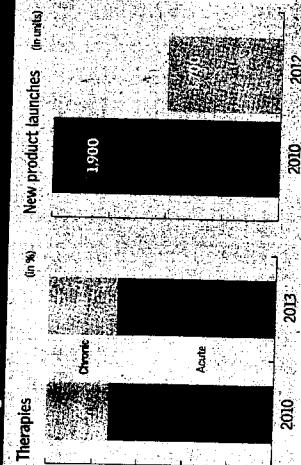
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Growing trend



“Short-term industry challenges would get sorted out in time, and as the new Government gets elected next year. But companies in it for the long-haul will continue to grow.”
Hasit Joshipura, MD, GSK (India)



“Export data for the first six months is not encouraging. We hope industry recovers to reach the 10 per cent growth (in dollar terms).”
P.V. Appaji, Director-General - Pharmexcil

clinical trials

This is the fifth in a series of year-enders on different sectors of the economy.

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