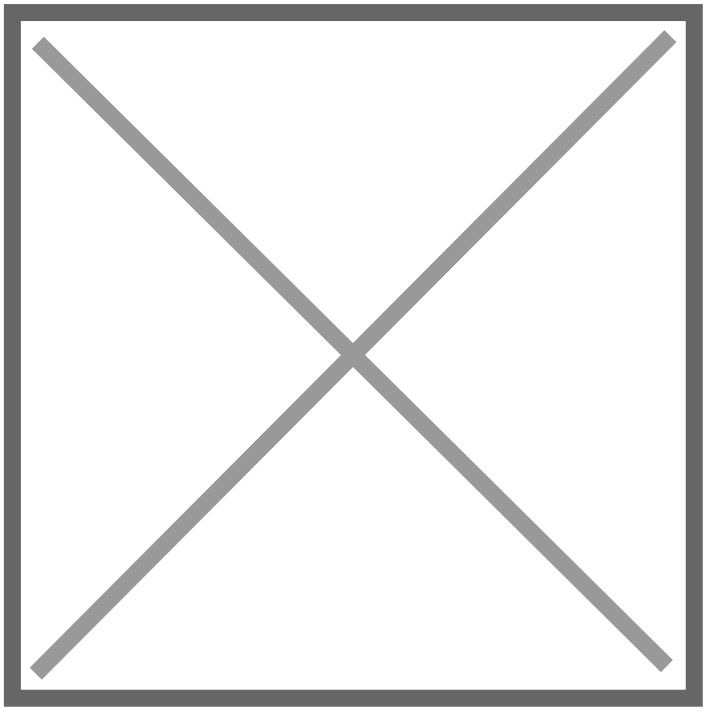


Takeda chief suggests 10-year strategy for life sciences industry

07 July 2007 | News



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Stressing the need for aligning in tellectual property (IP) strate gies with corporate plans, leading Japanese pharma industry leaders urged the players to evolve a 10-year strategic plan to overcome the challenges expected in 2010 when a large number of drugs go off patent in Japan.

Handling of foreign clinical data

Before ICH

MHW Director General Notification in 1985

- Foreign Clinical data with credibility and quality is acceptable as NDA data. However, the following three types of studies, in principle, should be conducted in Japan - pharmakokinetics studies, dose-response Studies, and well-controlled studies to demonstrate the drug's efficacy and safety

After ICH-E5

MHW Director General Notificaion in 1998 based on ICH E-5 guidelines.

- Foreign clinical data prepared according to GCP is acceptable as NDA data.
- The extent/content of domestic clinical data to assess the possibility of using foreign data in evaluating the drug's efficacy in Japanese population should be decided based on ICH-E5 guideline.

Delivering the keynote address at the Interphex Japan 2007 conference, Dr Hiroshi Akimoto, managing director, Takeda Pharmaceuticals Co, the $11 billion leader, said companies have to take a long-term view of the onrush of generics and

strengthen their IP departments to survive the 2010 challenge. He was advising the industry on the 'Global and intellectual property strategies of pharmaceutical companies - Patent wars in drug discovery towards 2010.'

In the near future, a company's IP strategy can make or break its prospects. The IP division has to be treated as a profit center and its impact on innovation and profitability measured to get better value for the organization, Dr Akimoto said.

At the same time, he told over 1,000 top leaders of Japanese pharma industry that they should also be keeping track of how their competitors were handling the IP-related issues.

Intangible assets of a company like IP were more valuable and should be monitored and improved continuously within the organizations, he advised.

In Japan, the government policies in the recent years has been emphasizing on greater thrust to innovation in all sectors, including pharma. A special committee of the government and industry was drawing up the plans in 2007 to create, protect and leverage the country's IP investments with a series of new rules and guidelines, he pointed out. At the same time the goal of the new policy was to use IP strategically to ensure economic and social goals of Japan, he emphasized.

Giving the example of Takeda, which is the country's largest company, but ranked 15 or 16 globally, he said Japanese companies have to look at globalization to increase their market positions. "Can we compete globally? That is the challenge for all the pharma companies," he said. According to Dr Akimoto, Takeda was in a better position with 51 percent of its sales coming from the US, but still everyone has a lot to do.

Thin pipeline

At another key note address, on the strategies for the industry, Masatake Miyoshi, managing director, Merrill Lynch Japan Securities, pointed out that the small and medium pharma enterprises in Japan did not have a long pipeline of promising drugs. The pipeline was not very strong even among the top 10 companies, he said. There are very few companies with more products in phase 3, which may go on to become successful, at this stage. This was a case for worry, he said.