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MSD Japan head: Regulatory bodies are purposely delaying approvals

July 17, 2013 | Analysis | By BioSpectrum Bureau



The entire world is worried about drying up of research pipelines and continued decline in research productivity. This major global concern was the core issue that was brought to light at the at the 7th in-Pharma Japan and 26th Interphex Japan, which was held from July 10-12, 2013, at Tokyo Big Sight, Japan.

While taking about the need for continued innovation, Mr Tony Alvarez, representative director and president, MSD (Merck Sharpe Dohme) KK, Japan, pointed out that it was not enough to develop drugs, if those individuals who are in need of it do not have access to it. He further stressed that the lowering of research productivity is making it increasingly difficult for firms to invest in innovation due to the lack of return on investment.

Speaking to BioSpectrum at the event, Mr Alvarez said, "R&D productivity is getting worse and is reduced by half every nine years. Innovation has become an expensive and complicated business."

Mr Alvarez highlighted that regulatory bodies across the world are appending to the pain by making it difficult for life science companies to bring their drugs to the market. He pointed out that the regulatory bodies, including the US FDA, are purposely placing hurdles in the path of drug discovery and commercialization processes in order to control the cost of drugs by controlling their access in the market.

Mr Alvarez, while narrating a recent incident said that MSD was all set to launch a crucial drug in the market but had to halt the same as the US FDA changed its evaluation policy for the drug at the last moment and asked MSD to provide additional data regarding the drug. He further highlighted that this led to an instant delay of six months in the process, the cost of which translated in millions of Dollars.

Mr Alvarez pointed out that while companies have several market opportunities in the form of aging population, globalization and advances in technology, the attitude of "control cost by controlling access" shown by regulatory bodies will eventually lead to stifled innovation.