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# Low R&D output, patent cliffs drives big pharma nuts

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**High expenditure, low R&D weakens industry**

**Singapore:** According to the latest global report from industry experts, GBI Research, low R&D productivity, combined with the patent cliff and a stringent US FDA approval process, is resulting in climbing expenditure without the corresponding output.

According to a new report titled 'Accelerating Drugs to Markset - Despite Challenges, Adaptive Clinical Trials Reduce Drug Development Costs and Time to Market', by market analyst GBI Research, despite efforts by pharmaceutical firms to cut down on costs, R&D expenditure expanded at a compound annual growth rate (CAGR) of six percent from $26 billion in 2000 to $50 billion by the end of 2011. Conversely, the number of new molecular entities (NME) approved during this same period has dropped on average, decreasing at a CAGR of one percent.

R&D is a core and integral part of the pharmaceutical industry, but poor productivity means that there may soon be a drought in the R&D pipeline. GBI Research estimates that currently as much as 55 percent of the entire late-stage pipeline is made up of life cycle management (LCM) projects, while a 28 percent share of the industry's top 20 companies' pipelines is devoted to LCM research.

To compound the frustrations of the industry, the FDA adopted a stricter drug approval policy. Following controversies regarding products such as Vioxx and Exubera, as well as product recalls for made in China drugs, the agency has been more cautious in analyzing the risks and benefits of drugs before approving them, slowing down or cutting out potentially marketable treatments.

Additionally, the patent cliff has damaged company revenues, severely curbing the selling power of blockbuster medications and opening the market to generics. The reduction in NME approvals has meant the big pharmaceutical firms are less able to offset the loss of revenue resulting from patent expirations, with new drugs offering therapeutic superiority to the generic versions of their predecessors.