

2016 sees lowest number of drug approvals in six years

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Singapore: 2016 was a disappointing year for new drug approvals with the US FDA issuing approval for just 22 new medicines for sale. The number of drugs that got approval has fallen sharply from the 45 drugs that gained approval in 2015 and is the lowest since 2010. Across the Atlantic, the European Medicines Agency recommended 81 new prescription products against a 2015 total of 93. Unlike the FDA, the EMA includes generic drugs in its list.

The fall in new drug approvals indicate that the pharmaceuticals industry may be returning to more normal productivity levels after a spike in approvals in 2014 and 2015, when the haul of new drugs reaching the market hit a 19-year high.

At a recent conference, FDA's director Mr John Jenkins highlighted that several factors led to the fall in the approval rate in 2016. Notably, five new drugs that had been scheduled for approval in 2016 ended up winning an early green light at the end of 2015. There was also a decline in drugs being filed for approval and the FDA rejected or delayed more applications in 2016 than in the previous two years.

Some of the delayed drugs may yet go on to win approval in 2017, including Roche's multiple sclerosis treatment Ocrevus and Sanofi and Regeneron's sarilumab for rheumatoid arthritis.

With recent advances many firm have great development pipelines and remain upbeat about the hunt for new medicines, however it is still challenging to get new drugs through the approval process and to secure a decent financial return once they are launched, given resistance from healthcare insurers and governments to the rising cost of medical treatment.

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Increasing political pressure over the high prices of many modern medicines is a growing challenge at a time when biotech and pharma companies are developing more drugs targeted at niche patient populations.

The issue is exemplified by the last drug to win FDA approval in 2016. Spinraza, from Biogen and Ionis Pharmaceuticals, is the first medicine to treat patients with spinal muscular atrophy, a rare and often fatal genetic disease. It comes at a huge cost of \$125,000 per dose.

That price, implying a total cost of \$625,000 to \$750,000 for patients in the first year and \$375,000 in subsequent years, is likely to invite "a storm of criticism, up to and including Presidential tweets", according to Leerink analysts.

Though President-elect Mr Donald Trump has vowed to bring down drug prices giving the industry and consumers new ray of hope, the effect of the new government is yet to be seen.