Medical Xpress

First-of-a-kind drug approvals continued rise in 2015

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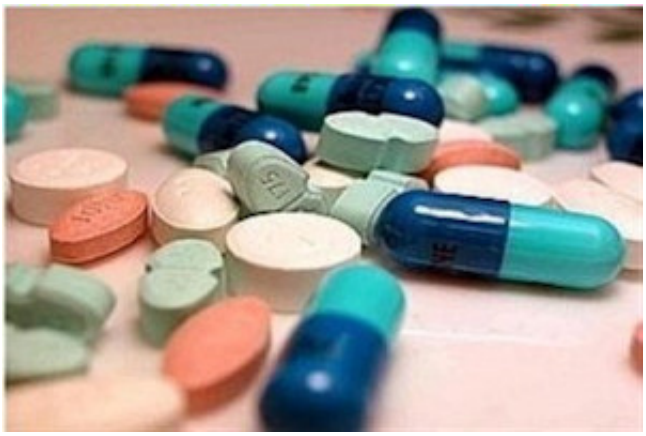

Various pills. Credit: Wikipedia

Approvals for first-of-a-kind drugs climbed last year, pushing the annual tally of new U.S. drugs to its highest level in 19 years.

The rising figures reflect an industry-wide focus on drugs for rare and hard-to-treat diseases, which often come with streamlined reviews, extra patent protections and higher price tags.

The Food and Drug Administration approved 45 drugs with never-before-sold ingredients in 2015, edging past the previous year's tally of 41, which had been the highest number since 1996.

FDA drug approvals are considered a barometer of industry innovation

and the government's efficiency in reviewing new therapies.

While the trend toward specialty medicines is good news for industry and patients, it is likely to stir debate about rising prescription drug prices. That issue has become a top concern for consumers, a subject of congressional scrutiny and even an issue on the presidential campaign trail. Democratic candidates Hillary Clinton and Bernie Sanders have both outlined proposals designed to curb prices.

The FDA is not allowed to consider prices when approving medicines, though some experts argue it should.

One of the most expensive drugs of the year was Vertex Pharmaceuticals' Orkambi for cystic fibrosis, priced at $259,000 for a year's supply. The drug improves lung function in patients with the deadly inheritable disease, which causes the buildup of sticky mucus throughout the body. Pfizer's breast cancer drug, Ibrance, was priced at $118,200 per year, which was typical of new cancer drugs. Even some drugs for more prevalent diseases came with high price-tags: Bristol-Myers Squibb's hepatitis C pill, Daklinza, costs $63,000 for a 12-week regimen.

Analysts say drugmakers are getting better at picking the most promising drugs in their research and development pipelines.

Between 2007 and 2011, only one in 19 drugs entering early-stage testing actually reached the market, according to industry data analyzed by Bernstein's Tim Anderson. Today, one in 13 early-stage drugs make it to market.

"These improvements hopefully reflect the pay-off from the industry's conscious decade-long efforts to 'turn around' R&D," Anderson told investors in a research note last year.

Still, drugmakers continue to face R&D challenges. Anderson notes that the overall time to discover and develop one new drug has been rising for more than a decade, currently averaging about 14 years. The figure was about 11 years in the late 1990s. The increased development time has been driven by the growing complexity of drug trials and demands for more data from health insurers.

A separate report from Deloitte suggests the largest pharma companies could learn from the R&D strategy of their mid-size competitors, who tend to focus on a particular family of diseases or conditions. These smaller companies tend to have lower R&D costs and higher sales per product, according to Deloitte.

"Our analysis indicates that companies who maintain a consistent therapy area footprint are projected to deliver higher R&D returns," the company states.

Despite the difficulties of drug development, experts expect the approvals trend to continue. IMS Health predicts 225 new drugs will be approved worldwide between 2016 and 2020.

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