Evaluate Vantage

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US FDA adds quantity to new drug approval speed

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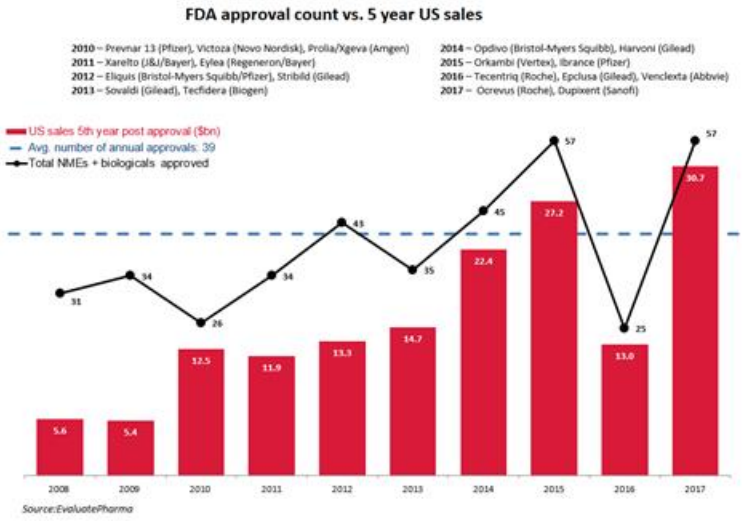
2017 drug approvals matches 2015 record, but forecast five year sales excel.

Last year saw the US recover from its 2016 new drug approvals slump, at the expense of only a slight increase in the average time taken to complete reviews.

These are the key findings from 2017's tally of US approvals, which amount to 57 new small molecules and biologicals, matching the record 2015 had set for this century (see charts below). Even better for industry bulls is that combined fifth-year US sales of drugs approved last year outstrip those of the class of 2015, positioning 2017 as a year to remember – if analyst forecasts hold up.

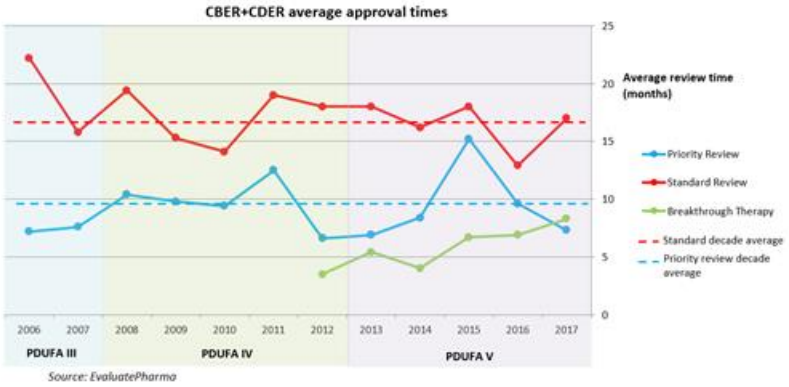


As such, any fears that biopharma might have had over the Trump administration's new FDA commissioner seem to have been misplaced. Scott Gottlieb, appointed to the post last May, has shown himself to be industry-friendly, presiding over a period during which the FDA seemed happy to leave a drug's economic prospects down to payers rather than troubling itself with unconvincing efficacy data.

Fast

While 57 new drug approvals is a joint 21st century record, much of it will be down to luck over a given 12-month period. Still, fast approvals for products like the novel CAR-T therapies Kymriah and Yescarta will have helped bump up the numbers.

Indeed, applications with priority review – which both Kymriah and Yescarta boasted – sailed through in an average of 7.3 months, the fastest since 2013. Conversely, the average time for applications under standard review went back up to that seen two years ago, while overall review times amounted to 12.3 months, slightly above 2016's total, with the caveat that the total numbers are relatively small.



The annual report from the CDER, the FDA department responsible for reviewing applications for small molecules and some biologicals, boasted that at least one expedited development and review method had been used in filings for 61% of all novel drugs it approved in 2017.

First-cycle approval, without requests for additional information, was achieved by 85% of applicants. And, given the earlier reports of the FDA collapsing under the strain of its workload, the statistic about which the agency might be most proud is that the CDER met its target PDUFA date in 100% of applications.

For investors, even more important than absolute approval numbers will be the economic potential of those new drugs. And here 2017's forecast beats that expected for 2015's approvals, by $30.7bn in total versus $27.2bn.

True, this could largely be down to the sellside becoming increasingly positive in a bull market, but it cannot be denied that the class of 2017 will include such expected blockbusters as Roche's Ocrevus and Sanofi's Dupixent.

Perhaps only a big commercial failure among the current crop could make analysts more cautious about upcoming projects. But at least getting drugs onto the market does not appear to be a problem – and it could get easier as the effects of PDUFA VI and the 21st Century Cures Act filter through.

Should this pace of approvals continue and the FDA's apparent lenient stance persist, it will take issues beyond the regulatory sphere to hit the current mood of optimism.

NME approval numbers and time over the past decade								
	Priority review		Standard		Breakthrough therapy		Total	
Year	Number	Avg time (mth)	Number	Avg time (mth)	Number	Avg time (mth)	Number	Avg time (mth)
2017	15	7.3	25	17.0	17	8.3	57	12.3
2016	11	9.6	8	12.9	6	6.9	25	10.0
2015	17	15.2	29	18.0	11	6.7	57	15.0
2014	13	8.4	23	16.2	9	4.0	45	11.5
2013	9	6.9	24	18.0	2	5.4	35	14.0
2012	14	6.6	28	18.0	1	3.5	43	13.7
2011	16	12.5	18	19.0	-	-	34	16.0
2010	10	9.4	16	14.1	-	-	26	12.3
2009	13	9.8	21	15.3	-	-	34	13.2
2008	9	10.4	22	19.4	-	-	31	16.8
Source: EvaluatePharma								

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