How Covid failed to derail the FDA

Average US review times match absolute approval numbers in remaining unaffected by the Covid pandemic.

Despite Covid-related delays to some FDA approvals – those of Jemperli and Breyanzi being two cases in point – average US review times showed no signs of dipping either during the pandemic or in the early months of the world’s subsequent opening up.

It was already known that the absolute number of novel US drugs approved actually picked up slightly during the pandemic, and now an analysis of Evaluate Pharma data suggests no slippage in the time taken to review these, either on a standard or priority basis. The data will be of interest now that the FDA faces a challenge to its accelerated approval pathway.

That challenge comes in the form of the Accelerated Approval Integrity Act, unveiled earlier this month, as questions persist over the FDA’s approval of questionable drugs like Aduhelm and Exondys 51. The measure seeks to put more pressure on the FDA to pull conditionally approved therapeutics whose makers do not swiftly confirm their benefit.

For now, however, the trend is clear: the 58 novel drugs greenlit last year by the FDA’s CDER and CBER were approved in an average review time of just under 10 months. This speed represents a steady upward trend over the past 10 years or so; in 2014, for instance, the average FDA review time was 17 months, according to Evaluate Pharma data.
Though Covid was clearly a factor in 2020-21 the numbers suggest that, by and large, the FDA worked around the various problems it presented.

The chart above is complicated slightly by Pfizer/Biontech’s Covid vaccine Comirnaty, which was approved formally last August, some eight months after first becoming available under an emergency use authorisation. The numbers do not include Moderna’s Spikevax, which was only approved two months ago, though like Comirnaty it has been available under EUA since December 2020.

Overall, as has already been reported, absolute US FDA approval numbers rose last year to 58 novel drugs, up from 49 in 2019, but down slightly on the year before that. Interestingly, despite variability in the number of drugs approved, the total sales these are expected to bring in is holding fairly steady.

Thus fifth-year US revenue, which for last year’s crop of approvals means Evaluate Pharma sellside consensus for 2026 sales, stands at $24bn for drugs approved in 2021, versus $19bn and $30bn for those greenlit in 2020 and 2019 respectively.

Still, there are a few caveats here, most notably the absence of significant contributions from Covid vaccines. Spikevax and Comirnaty alike are notable for being mega blockbusters – with combined global sales of $106bn in 2021-22 – but by 2026 their revenues are expected to fall to the single-digit billions of dollars.

Other drugs approved last year expected to become 2026 blockbusters include Novartis’s Leqvio, Argenx’s Vyvgart, Bristol/Bluebird’s Abecma and Amgen’s Lumakras; the last two are hardly shoo-ins for billion-dollar sales generators.

Then there is Biogen’s Alzheimer’s drug Aduhelm, controversially approved on an accelerated basis last year. Aduhelm consensus sales forecasts have fluctuated wildly, along with its prospects for broad US reimbursement, and for simplicity they have been omitted from this analysis.
28/03/2022: This article has been updated to correct the 5th year sales for 2021 approvals.