

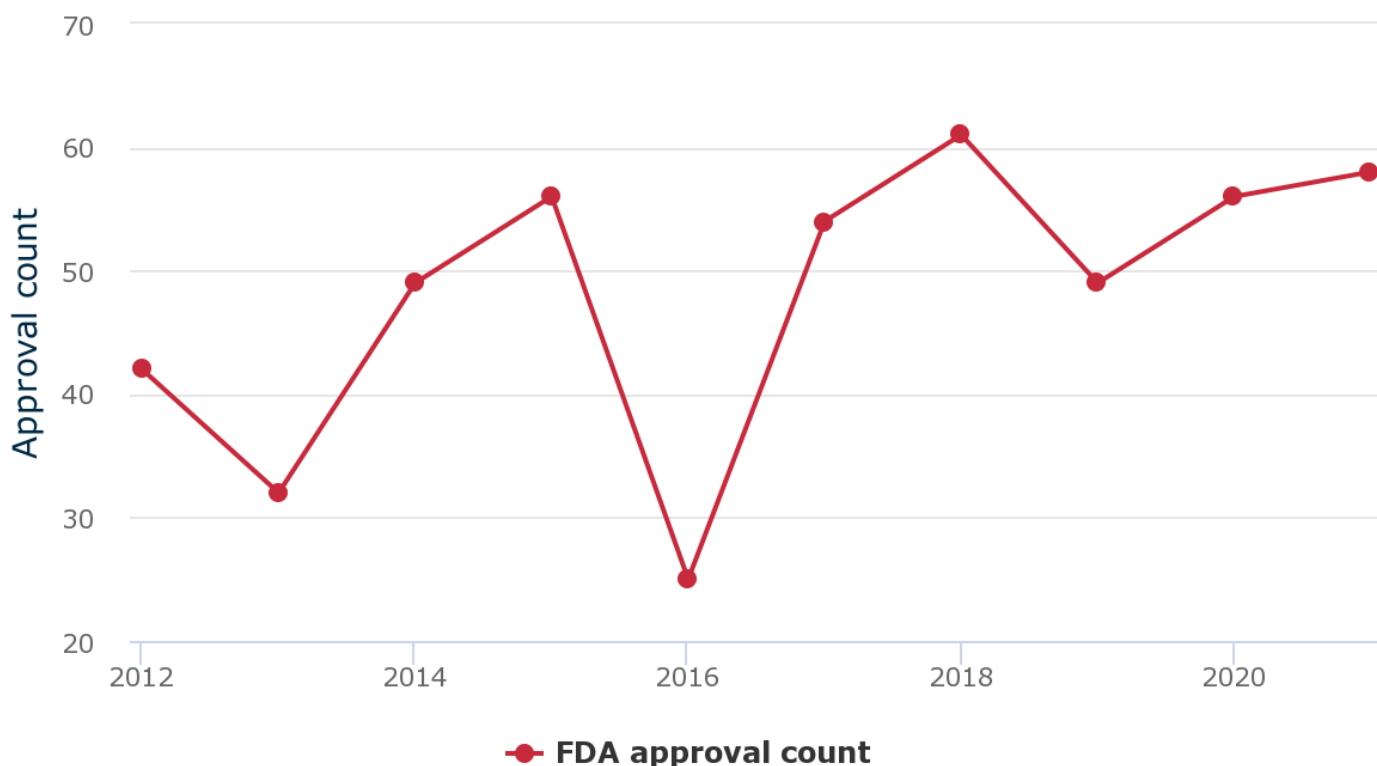
The FDA brushes off the pandemic with a pick-up in novel drug approvals



Amy Brown

The US drugs regulator approved 58 novel drugs last year, the highest number for three years and well above the 10-year average of 48. With travel limitations blamed for decision delays in a number of cases, Novartis's Leqvio and UCB's Bimzelx included, this uptick could presumably have been steeper under more normal conditions. The only Covid product included in this count is Biontech and Pfizer's Comirnaty; all the other pandemic-related projects are on the market under emergency use authorisations, rather than full approvals. The mRNA vaccine is almost certainly going to become last year's biggest approval commercially speaking, though by 2026 sales are forecast to have dipped substantially. This time last year Biogen's Aduhelm was looking like the class of 2021's biggest seller, according to fifth-year sales as predicted by sellside analysts. [Should last week's punitive US coverage decision hold](#) consensus is likely to drop to close to zero. That still leaves plenty of potential future blockbusters that arrived on the market last year, according to *Evaluate Pharma's* consensus in the table below. That said, it is worth remembering that several of these projects need to win expanded labels, or carve out share in highly competitive therapy areas, to reach these lofty levels.

Ten years of FDA approvals (CDER + CBER, therapeutic agents only)



Predicting great things: 2021's arrivals with blockbuster potential

Product	Company	Description	2026e US sales
Leqvio	Novartis	siRNA-based anti-PCSK9 for high cholesterol; approved in heterozygous familial hypercholesterolaemia and atherosclerotic cardiovascular disease.	\$1.7bn
Abecma	Bristol Myers Squibb/Bluebird	Anti-BCMA Car-T cell therapy; approved for B-cell and follicular lymphomas	\$1.4bn
Comirnaty	Pfizer	Covid-19 vaccine	\$1.4bn
Tezspire	Amgen	Anti-TSLP MAb; approved in severe asthma	\$1.2bn
Vyvgart	Argenx	Anti-FcRn MAb for IgG-mediated autoimmune diseases; approved in myasthenia gravis	\$1.2bn
Lumakras	Amgen	Kras G12C inhibitor; approved in non-small cell lung cancer	\$1.2bn
Lupkynis	Aurinia	Calcineurin inhibitor; approved in lupus nephritis	\$1.1bn

Source: Evaluate Pharma.

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