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2022 FDA approval number dips: a COVID-19 hangover?

The number of FDA approvals in 2022 was the second lowest since 2014, when the annual number of approvals first spiked substantially compared with the previous decade (Fig. 1). The FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research approved 43 new therapeutic drugs (NTDs; see Fig. 1 for the definition), including the second COVID-19 vaccine to secure full FDA approval, Moderna's Spikevax. This count is below the average of 51 NTDs per year for 2014–2021, perhaps partly due to pandemic-related and other macroeconomic stressors, including the impact of COVID-19 on clinical trials and resource constraints at biopharma sponsors and the FDA.

The sum of projected annual peak sales for NTDs approved in 2022 is US$69 billion (Fig. 1), which is below the $89 billion for 2021 approvals, and the $76 billion average for 2014–2021. COVID-19 vaccines and treatments with Emergency Use Authorization — Johnson & Johnson's Ad26.COV2.S and Pfizer's Paxlovid in 2021, and Novavax's Nuvaxovid and Eli Lilly's bebtelovimab in 2022 — add $26 billion for the 2021 cohort and $9 billion for the 2022 cohort, respectively.

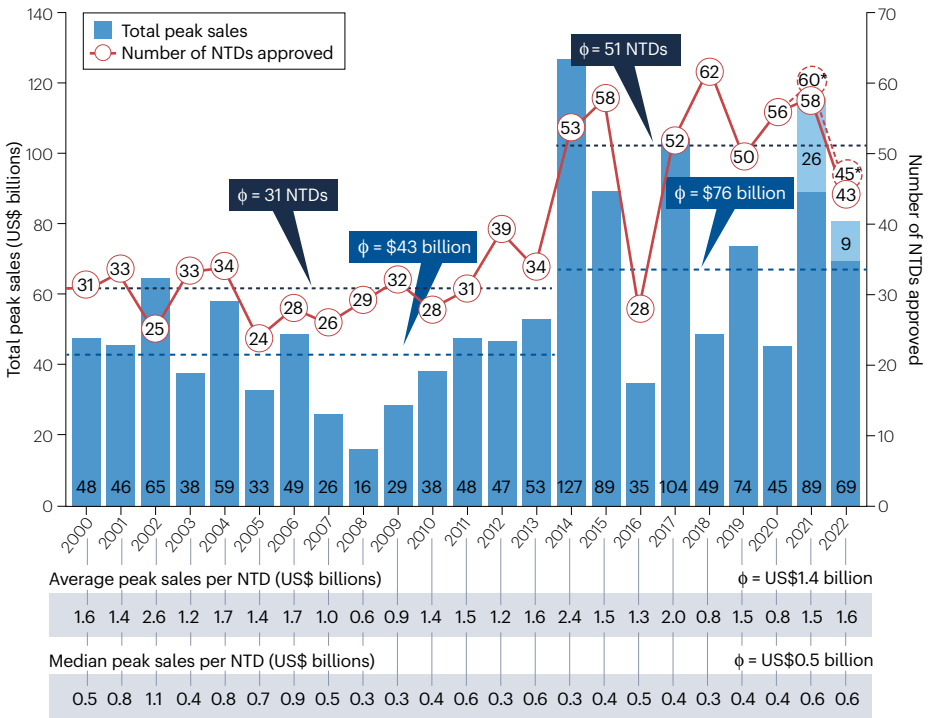

Fig. 1 | FDA approvals of new therapeutic drugs and aggregate projected peak global annual sales: 2000–2022. We analysed 2022 FDA approvals of new therapeutic drugs (NTDs), defined as new molecular entities approved by the FDA's Center for Drug Evaluation and Research and Center for Biologics Evaluation and Research, but with two adjustments: first, we excluded diagnostic imaging agents; and second, we included combination products with at least one new molecular entity as an active ingredient. For 2021 and 2022, we have also added COVID-19 vaccines and treatments that received Emergency Use Authorization, indicated with asterisks and a dashed red line, and with sales in light blue in the bars (Ad26.COV2.S and Paxlovid in 2021, and Nuvaxovid and bebtelovimab in 2022. Comirnaty and Spikevax received full FDA approval in 2021 and 2022, respectively). Averages (ϕ) for the two periods indicated with dashed blue lines are shown. The analysis is based exclusively on approvals by the FDA and the year in which the first indication approval took place. All peak sales values were obtained from EvaluatePharma and were inflation-adjusted to 2022, using standard global GDP-based inflators sourced from the Economist Intelligence Unit. To arrive at peak sales for each NTD, we reviewed historical actual sales, as well as the full range of forecast sales that are available from EvaluatePharma, and selected the highest value. Sources: EvaluatePharma, FDA and Boston Consulting Group analysis.

Despite the lower approval number, average and median peak sales forecasts per NTD for 2002 are at $1.6 billion and $0.6 billion, respectively. This is on par with 2021 and is driven by several forecasted blockbusters beyond COVID-19, including Eli Lilly's dual GIP/GLP1 receptor agonist tirzepatide and Roche's VEGF × ANG2 bispecific antibody faricimab. Overall, 35% of last year's NTDs are forecasted to reach blockbuster status, up from 22% in 2021.

Oncology and anti-infectives — including the COVID-19 vaccines — continue to be the largest therapy areas for NTDs, accounting for 29% and 13% of approvals, respectively. Due to the revenue generated by the COVID-19 vaccines, anti-infectives deliver 43% of the value, with new oncology products contributing 16%. In 2021, anti-infectives had an even higher value share of 64%, whilst oncology contributed 10%.

Overall, we are convinced that learnings from the pandemic and a better understanding of disease biology, in combination with pipelines full of promising candidates and novel technology platforms, will have a positive impact on future drug approvals, in line with our positive outlook from early 2021 (*Nat. Rev. Drug Discov.* **20**, 92; 2021). This should lead to a recovery from what may be a COVID-19-related hangover.

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Competing interests
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