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Merck leads rivals in novel drug approvals

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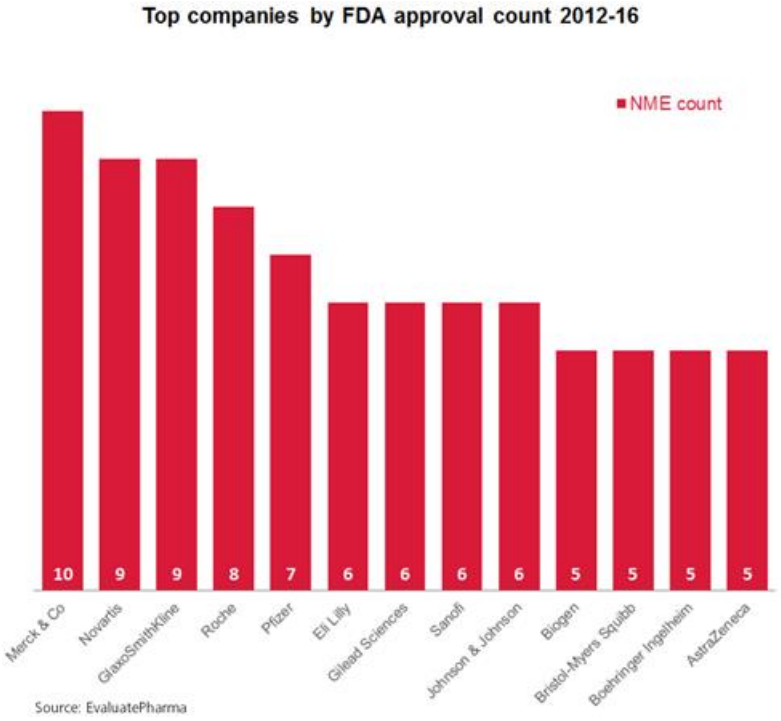
With 10 NMEs approved this year Merck pulls ahead of rivals Novartis and GSK.

The annual tally of novel drug approvals is often taken as a barometer of productivity, and an analysis of the companies most responsible for bringing these medicines to market reveals some obvious leaders.

Merck & Co heads the large pharma groups that naturally dominate this analysis, with 10 new molecules approved by the FDA in the past five years; Novartis and Glaxosmithkline follow with nine each. Of course not all of these compounds were developed internally, many having been licensed in or acquired. But revenue is revenue, whatever the source, and the analysis also shows those losing out, pointing to a dry spell for Sanofi and Astrazeneca (see graphs below).



This analysis collates all CDER and CBER novel drug approvals over the five years from 2012 to 2016, though it does exclude certain blood products and imaging agents. Where a product was bought or licensed before approval, the acquirer is counted as the “owner” of the approval, even if this happened shortly before the regulatory action.

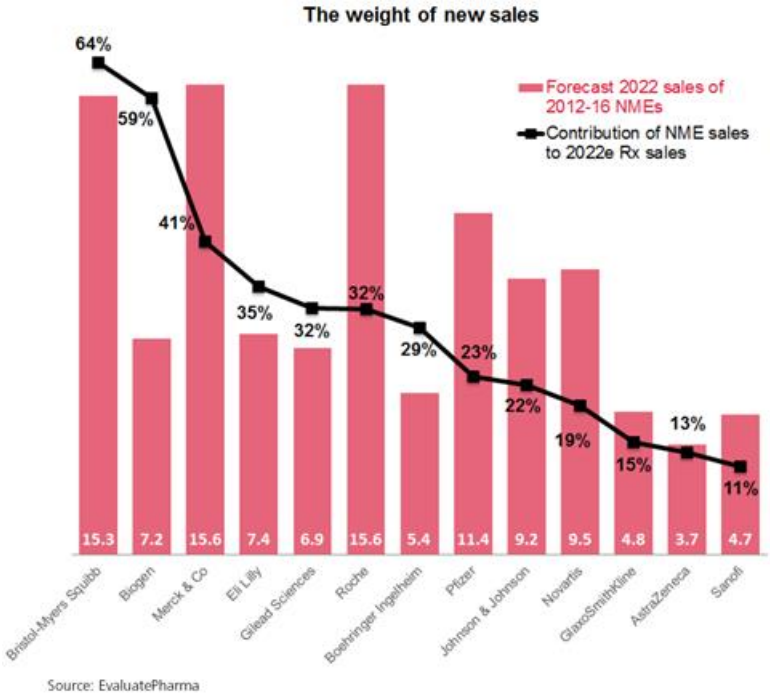
Examples of this include Eucrisa, which was bought by Pfizer six months before the FDA granted a marketing licence, and more dramatically Esbriet, which Roche snapped up just two weeks ahead of the green light.

With these caveats in mind, the analysis suggests that Merck & Co has had double the success in bringing new products to market in the past five years, versus the likes of Bristol-Myers Squibb and Astrazeneca. This is a simplistic measure, of course, and quality matters more than quantity. The analysis below looks at the sales potential of these new arrivals.

Merck again stands out with the most valuable cohort of new drugs in the past five years, at least according to forecast sales in 2022. These products are expected to account for 41% of the company’s prescription drug sales that year, according to *EvaluatePharma*, a sizeable proportion relative to peers.

Keytruda, one of the most important oncology launches of the past five years, accounts for a huge proportion of this. The drug is expected to rake in $12bn in 2022 to become the third-biggest selling product globally.

Bristol-Myers and Roche are not far behind. The former counts its rival checkpoint inhibitor Opdivo and blood thinner Eliquis as its most important new launches of the past five years, while the Swiss pharma giant can boast of four blockbusters: Perjeta, Tecentriq, Gazyva and Kadcyla.



Still, in terms of overall importance Bristol stands out, with these new products accounting for almost two thirds of sales in five years’ time. Many consider this to be an over-reliance, and the company is under pressure to restock its late-stage pipeline.

At the other end of the scale are Astrazeneca and Sanofi, whose recent launches are seen making a much smaller impact on future sales. This could all change if Astra’s immuno-oncology ambitions come to fruition. And US approval for Dupixent in late March relieves some pressure on the French pharma giant, although many still see it in urgent need of other future revenue streams.

Interestingly Gilead, a company that has been heavily criticised for failing to replace its fading hepatitis C franchise, does not stand out in this analysis as a laggard.

These data present only a few ways to look at the complex picture of R&D productivity, which many believe has improved over recent years. And each company of course faces a unique set of difficulties. All, however, are dealing with new pricing realities, which are forcing a focus on clear medical need and differentiation. The quality of these new drug approvals has perhaps never been so important.

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