Evaluate Vantage

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Better out than in as pharma continues to find value externally

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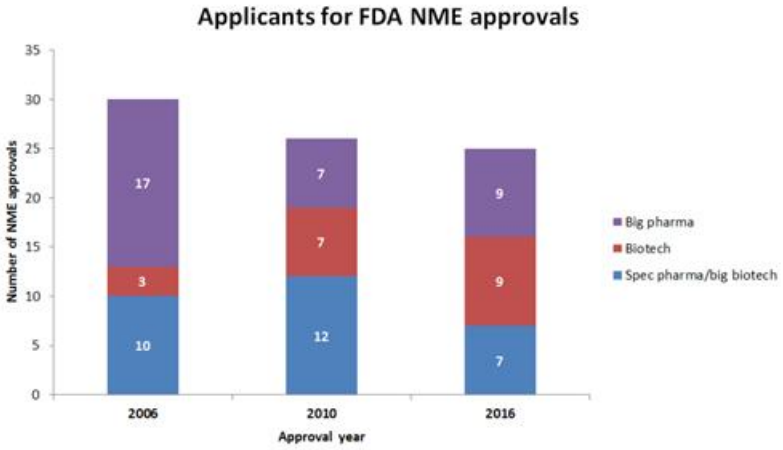
Big pharma's fluctuating fortunes with R&D productivity are no secret and recent high profile pipeline blow-ups such as Eli Lilly's solanezumab demonstrate this all too graphically. As such, it is no surprise that pharma companies are not averse to a little external help when it comes to stocking their portfolios.

This analysis using *EvaluatePharma* data shows that the number of NME applications for FDA approval by big pharma groups has fallen substantially in the last 10 years. In 2006, of the 30 NMEs approved by the FDA 17 were filed by big pharma, but this has fallen dramatically to just nine of the 25 new products filed in 2016. Even within that reduced number externally sourced products make up roughly half of these NMEs, showing big pharma's continued reliance on licensing (see charts below).

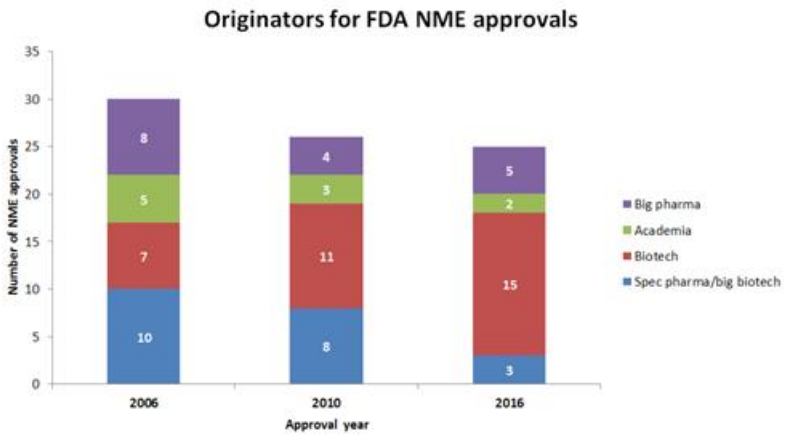


Source: EvaluatePharma

The data also show that big pharma's loss very much appears to be biotech's gain. Over the 10-year period studied the number of NME applications from biotech companies trebled, from three to nine. One potential reason behind the rise is the biotech boom that enabled many biotechs to raise the funds to take products all the way from development to commercialisation.

In 2016 Intercept, Elusys Therapeutics, CSL and Acadia Pharmaceuticals all managed to not only file their own products but also bring them to market. The fact that many of the treatments were either niche vaccines or for rare diseases helped.

Elusys benefited from its relationship with the US government when seeking approval of its injectable treatment for inhaled anthrax, while CSL managed to obtain orphan drug status for its factor IX treatment Idelvion. Controversially, Sarepta also managed to get its Duchenne's muscular dystrophy product Exondys 51 approved last year *(Sarepta, patients win – but what of regulatory oversight?, September 19, 2016).*



Biotechs overtook all other groups when it comes to originating approved NMEs: 15 of the 25 new drugs approved in 2016 were discovered in the labs of biotech companies. This again indicates that big pharma, and increasingly big biotech, are outsourcing more and more of their R&D efforts.

And in a time of falling R&D expenditure among many big pharma groups, bringing in external assets can have numerous benefits. This strategy can increase flexibility in allocating resources to meet demand, lower the risk of entering a new therapy area and expand a company's global reach.

Back to school

Although declining, drugs originating in academic institutions continued to provide a source of NME approvals. Notable contributors include the University of Queensland, one of the creators of Merck & Co's Gardasil.

While academia has held relatively steady over the last 10 years alongside big pharma, the number of approvals from speciality pharma and big biotechs has dipped severely, falling from 10 in 2006 to a meagre three in 2016.

It has not, however, been all bad news for pharma and its internal R&D efforts. Some of the biggest-selling NMEs in the analysis cohort came from big pharma's own labs. Boehringer Ingelheim discovered and commercialised Pradaxa, which last year had sales of $1.65bn and if the products Pfizer acquired through its acquisition of Wyeth are counted as in-house, the US group can claim vaccine Prevnar 13, which is forecast to have sales of $5.54bn in 2022, as an R&D success.

And despite the huge disappointment of solanezumab, 2016 saw Lilly's dogged determination to avoid megamergers and invest in its own pipeline pay off with the approval of home-grown products Taltz in psoriasis and cancer drug Lartruvo. The trick now will be making these – especially Lartruvo – a commercial success in what are very crowded markets.

At the end of the day patients do not care where a drug was invented, only whether it works. However, for big pharma and big biotech it seems clear that innovation from smaller biotechs is not only outpacing their efforts, but is now a vital source of products for them.

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