

Prevailing Trends in Emerging Biopharma

Strong innovation, greater independence, increasing promotional pressure

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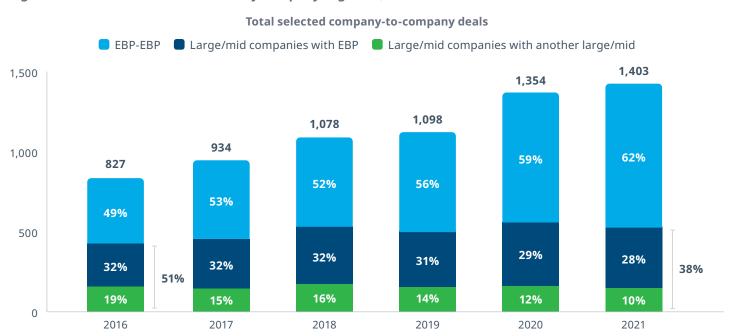
IQVIA presented the first in a series of virtual learning sessions for emerging biopharmaceutical (EBP) companies on the critical success factors for product commercialization. Following are highlights of the session, which focused on prevailing trends in levels of innovation, go-to-market strategies, and promotional spending.

A shift in how assets are brought to market

In recent years, there's been an explosion in the number of novel active substances (NASs) launched globally; the total introduced in 2021 (84) was double that of five years earlier. Additionally, EBPs are a major force in this trend as they originated 53% of all new drugs launched in 2021.

Most important, EBPs are changing how they elect to bring their products to market. An increasing number are opting to roll out their assets themselves (as opposed to outlicensing or partnering with another pharmaceutical company). Of the NASs originated by EBPs in 2021, three quarters (76%) were also launched by the EBP. This is part of a developing trend: in the U.S., the number of NASs launched by EBP originators has doubled in the last five years. At the same time, the number of EBPs striking deals with large pharma has dropped from 51% in 2016 to 38% in 2021. (See Figure 1.) This phenomenon is not exclusive to the U.S., as 42% of global NASs commercialized by EBPs originator companies in the last decade were also launched by those same companies in Europe.

Figure 1: Number and share of deals by company segment, 2016-2021



Source: IQVIA Pharmadeals, Dec 2021. Global Trends in R&D: Overview through 2021. Report by the IQVIA Institute for Human Data Science.



Key takeaway: There is a clear trend towards EBPs bringing their products to market themselves, causing a significant shift in the character of new launches

Launches during COVID-19 have underperformed historical launches

On average, all new products launched during 2020 – the first year that the COVID-19 pandemic had widespread impact – underperformed compared to historical launches. Collectively, their gross sales were 27% less than those of launches in 2016-2018 and 44% less than those of 2019. The impact of the pandemic appears to have carried over into 2021 launches, as data through August 2021 indicates that 2021 launches are underperforming 2020 launches by 12%.

WHAT SPECIFICALLY COULD ACCOUNT FOR THIS? IQVIA EXAMINED FOUR FACTORS:



Profile of the brands launched



Number of available patients



Promotional impact



Pressure from payers

Analysis eliminated the first two possibilities as valid explanations since there was no significant difference in the brands' profiles, and patient availability – while depressed in 2020 – rebounded in 2021. Thus, the reasons appear to be continued pressure from payers and reduced promotional impact.



Key takeaway: At a macro level, launches in 2020 and 2021 followed a softer trajectory than in prior years, likely due to pressure from payers and weaker promotional responsiveness

Big pharma is more successful at product launches than EBPs

According to IQVIA's analysis of launches spanning 2011 to 2020, large pharmaceutical companies have a stronger record of launch success than EBPs.¹ For large companies, 57% of the brands they commercialize are successful, compared to 39% for EBPs. Again, it is worth exploring the factors that could account for the difference.

Interestingly, the proportion of launched assets classified as innovative² is roughly equivalent between EBPs and large pharmaceutical companies (43% of launches vs 45% of launches, respectively). One noticeable difference, however, is in how well they optimize their respective promotional investments. Large companies spend, on average, \$45M on promotion to realize \$130M in sales in the first year. In contrast, EBPs spend, on average, a little more than \$20M on promotion to realize sales of \$40M.

How does partnering with a large pharmaceutical company change the outcome for EBPs? EBPs who launched with a partner averaged gross sales of \$57.2 M compared to \$29.9M for those who launched alone. Partnership, however, comes at the expense of revenue sharing. (Note: It is possible that large companies' higher performance could be attributed to their selecting assets that offer a larger opportunity.)



Key takeaway: EBP companies develop innovative products at roughly the same proportion as large pharmaceutical companies. However average revenues for EBP companies are typically smaller and yield a lower ROI on promotion spend. This difference will be impacted by the size of target patient population and hence opportunity in addition to company effectiveness in launch

- ¹Success rating is determined by gross sales, market share, competitive rank, and promotional effectiveness.
- ² Innovation score is based on improvements in efficacy, safety, dosing and administration compared to standard of care evaluated by IQVIA Clinical Team IQVIA proprietary launch database

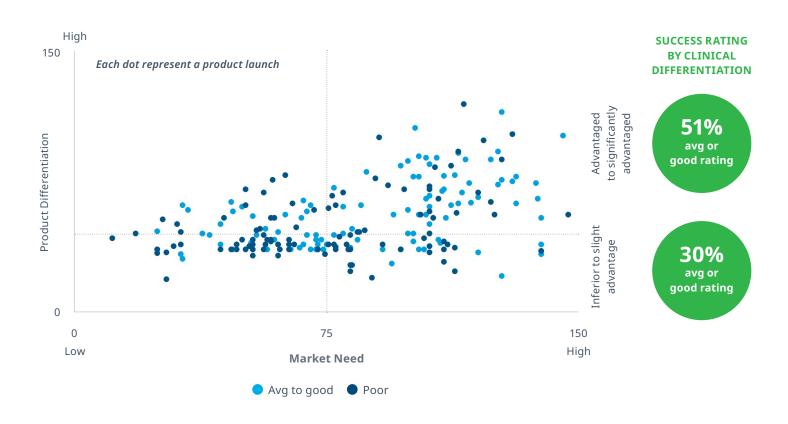
Critical success factors are different by launch archetype

While launch success can be ascribed to the characteristics of the market and the brand, these features are not 100% deterministic. Innovative products can fail to launch successfully if their strategy, execution, and investment are not optimal. By the same token,

some tremendously innovative products can have poor launches, as illustrated in Figure 2. If this were not the case, all the light blue dots (average to good launches) would cluster in the upper right quadrant of high product differentiation and high market need.

The lower left quadrant of low product differentiation and low market need would contain only dark blue dots (poor launches).

Figure 2: Launch performance by archetype for EBP-developed assets, 2011 -2020



Success rating is determined by the brand's ability to generate, gross sales, market share & competitive rank while being promotionally effective during the 1st 12 months of launch

Source: IQVIA proprietary launch database

IQVIA experience demonstrates that a **brand's differentiation** in the context of the **market need** is foundational to defining strategy and resulting tactics to drive a successful launch, as outlined in Figure 3.

Figure 3: Critical success factors by launch archetype



LOW NEED / HIGH DIFFERENTIATION

CORE NEED:

Highly experienced and strategic commercial resources

Low unmet need with High product differentiation

- · Disease/MOA awareness pre-launch
- Raise awareness of disease aCampaigns/Data to establish superiority
- · Aggressive positioning



HIGH NEED / LOW DIFFERENTIATION

CORE NEED:

Highly experienced and strategic commercial resources

High unmet need with High product differentiation

- · Disease/MOA awareness pre-launch
- · Optimized pricing
- Risk mitigation plan
- · Public policy activity
- · Advocacy engagement



LOW NEED / LOW DIFFERENTIATION

CORE NEED:

Ability to reach consumers broadly and effectively

Low unmet need with Low product differentiation

- Laser focus targeting (prescriber/patient)
- · Realistic expectations
- Services to differentiate product
- · Consumer focus access, co-pay offsets/DTC (US)

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HIGH NEED / LOW DIFFERENTIATION

CORE NEED:

Competitive share of voice and credibility with HCPs

High unmet need with Low product differentiation

- Consumer focus
- · KOL engagement & advocacy
- Competitive pricing
- · Services to differentiate product
- Patient segmentation & targeting
- Comprehensive evidence generation

PMSA Virtual University: Launch Archetypes: The Bedrock of Successful Launch Strategies, ©IQVIA, All Rights Reserved, November 2018

THUS, EBP COMPANIES MUST FOCUS ON FOUR PRIORITIES TO ENSURE SUCCESSFUL LAUNCHES:



Zero in on the appropriate patient type. Understand the patient journey in order to know where and how to best engage clinicians and other influencers of adoption



Build a strong economic proposition for both payers and patients. The access hurdle grows ever higher, and with limited portfolios, EBP companies may find it challenging to raise payer awareness and acceptance



Establish awareness programs pre-launch through a strong science platform



Optimize promotional channels to seek the highest possible ROI, leveraging both personal and non-personal engagement. While EBP companies may have constraints on their go-to-market resources, they have the flexibility to deploy an innovative and differentiated model



Key takeaway: Maximizing the probability of success for an EBP asset in a complex and competitive market will require understanding the asset's launch archetype and focusing on the critical success factors specific to that context

To read more about emerging biopharma's contribution to innovation, <u>download a copy</u> of our latest report from the IQVIA Institute for Human Data Science.