POINT OF VIEW

Embracing Uncertainty: Thriving in launch despite unexpected market dynamics

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It is inevitable that unforeseen events can impact the launches of new products; however, some events cause more disruption than others. Here we've outlined a few examples that we've encountered, and approaches that can minimize the overall impact to a brand.

1. Unexpected extensions in PDUFA date by the FDA, or extended review time by the EMA, often delay product launches.

These changes can be due to requests for updated data analyses, inspection of manufacturing facilities, or a data update to the submission. Because expected approval timing is often publicly communicated, delays can impact investors and the overall perception of the product. In some cases, a delayed launch could have a significant impact on marketing strategy. For example, it could prevent the rollout of a branded campaign at a major congress, requiring booth space to be repurposed at the last minute. For products where guideline recommendations are critical for HCP uptake, an extended review period could result in a concomitant delay in guideline inclusion. One example of this is vaccine recommendations in the US, which relies on Advisory Committee on Immunization Practices (ACIP) voting at meetings which occur only three times in a typical year. In a competitive landscape, a delay in approval or guideline inclusion could result in loss of first-mover advantage for a product, which may require a messaging shift.

Extensive scenario planning is critical to consider how messaging may need to change based on disruptions to launch timing. Creative campaigns should not rely on being the first-in-class product if competitors are not far behind. And alternative plans should be considered if a "big splash" cannot be made at a major congress; indeed, the COVID-19 pandemic has taught us that in-person events are not guaranteed and ultimately may not have the marketing impact that they once did.

2. Complications with launching a product that is not first-in-class can be further compounded.

This is especially true if new safety signals have been observed in an in-class competitor with real-world experience, potentially leading HCPs and patients to be hesitant about the entire therapeutic class. Because patient safety is always top of mind, we should anticipate how a competitor's safety profile may influence the Prescribing Information, Important Safety Information, and/or Summary of Product Characteristics while still in the prelaunch setting. Dexterous marketing materials should be designed to clearly communicate safety data and include sufficient space to accommodate necessary changes. Anticipation and agility with this process will help lead to efficient launches even when unexpected events occur.

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3. Pivotal trials may accrue slower than expected.

The resulting delays impact not only data disclosures and launch planning but may also cause investors and analysts to raise their eyebrows. The COVID-19 pandemic was a unique situation that resulted in a pause in trial enrollment for many major pharmaceutical companies,[1] and FDA and EMA guidance documents were published in 2020 detailing how to handle protocol deviations due to COVID-19.[2,3] The guidelines were designed to ensure maximum safety for patients while also enabling them to benefit from clinical trial participation. In particular, the steps outlined in the guidance documents were designed to protect patients who are immunocompromised, elderly, or otherwise particularly vulnerable to COVID-19.

As marketers, we can work with our clients to ensure that both HCPs and patients are aware of the continuing availability of clinical trials throughout the pandemic, with enhanced safety and flexibility for data collection. If slow clinical trial accrual does disrupt launch planning, we can use the extra time for additional disease state education, competitive scenario planning, and development of innovative, pandemic-friendly approaches to improve the experiences of HCPs and patients using a newly approved product for the first time.

4. A product may not launch at all due to a decision by the pharmaceutical company.

In this case, public relations strategies about the reason for halting clinical development are critical. If the company has other products for the same disease state in its pipeline, emphasis on its commitment to help patients through additional clinical research using other drugs will enable the decision to be seen in a more strategic light by investors. If the product was the only one that the company had in the disease state, then it is important to communicate how the data will be shared with the scientific community to advance overall knowledge in the space.

Here we have discussed just a few of the potential unforeseen events that can impact product launches. Contingency planning for these and other scenarios should be factored into prelaunch strategy.

To discuss how we can help your brand prepare for any potential impacts, contact your Evoke account lead or email us at **business@evokegroup.com.**

1. *Murphy J. Adapting to a new trial landscape. Evoke Group. May 5, 2020. Accessed February 8, 2022. https://www.evokegroup.com/thought-leadership/adapting-to-a-new-trial-landscape*
2. *Conduct of Clinical Trials of Medical Products During the COVID-19 Public Health Emergency. FDA. Updated August 30, 2021. Accessed February 8, 2022 https://www.fda.gov/media/136238/download*
3. *Guidance on the Management of Clinical Trials During the COVID-19 (Coronavirus) Pandemic. European Medicines Agency. Updated April 2, 2021. Accessed February 8, 2022. https://ec.europa.eu/health/system/files/2021-02/guidanceclinicaltrials_covid19_en_0.pdf*