
Launch Excellence – Moments of Truth

How clear, positive communications can
steer the product journey to success





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Introduction

It is the moment of truth. Launch is that critical time when the science, the clinical need, regulation and reimbursement coalesce with elegant symmetry or smash together like atoms colliding.

If Proof of Concept is a product's birth then launch excellence is its coming of age, navigating the turbulent teen years, when all the potential and hope is released and makes its way in the world.

How an organization frames its tasks, ethos and culture is critical to brand awareness, reputation and a drug's success and profitability in a fragmented and rapidly evolving environment.

The alchemy that fuses a good launch is clear, consistent communication that unites often disparate internal drivers and messaging and creates a strong value proposition for external engagements, across payers, patients, HCPs and regulators

This White Paper – the first in the three-part *Launch Excellence: Moments of Truth series* which examines the product story through pre-launch, launch and post-launch phases - explores the demands of the pre-launch phase and lays out learnings, strategies and areas of focus to help performance. It focuses on how communication is a vital tool to enrich MSL team engagements at summits and meetings with KOLs and enable the value of a therapeutic product to shine and connect with regulators, payors, physicians and patients.

Driven by an eminent panel of experts who have been involved in taking multiple products to market across a spectrum of blockbuster drugs to niche therapies, it delivers a unique insider view.

Across the series, we will learn from Catarina Santos, Executive Director Medical Launch Region Europe in Novartis, Cathrin Schaefer, BeiGene's Head, Market Access Europe, Marc van Unen, Business Unit Head, Cardiovascular for Bristol Myers Squibb, and Duncan Trew, an experienced pharma executive in Oncology and Emerging Markets.

Their testimony provides a rich commentary and guide on how communication can harness scientific excellence with commercial expertise to supercharge launches.



Start Early

The launch environment is changing and expanding with products spinning out across niche markets and multiple geographies. Blockbuster drugs have not vanished, but organizations are gearing up for a higher number of smaller launches each year rather than locking into almost annual set-pieces, which represents a new challenge for the internal organization.

An IQVIA report - *The Global Use of Medicines 2023* – predicts the global medicine market will expand at 3-6% per annum through to a value of \$1.9 trillion by 2027 with the key growth being executed in biotech, which is predicted to represent 35% of spending and ‘include both breakthrough cell and gene therapies as well as a maturing biosimilar segment’.¹

In 2022, the FDA’s Center for Drug Evaluation and Research approved 37 novel drugs, 20 of them first-in-class drugs, 12 of which achieved Fast Track status, indicating the dynamism of the sector.² The global orphan drugs market size is on an impressive parabola from \$1.4 billion in 2020 to \$4.35 billion by 2030, according to Allied Market Research statistics.³

It is a dynamic market outlook which, with the pandemic's aftershocks still resonating and the introduction of digital tools disrupting, makes pre-launch an increasingly challenging operational arena.

The keys to success play across a complex, fluid medley of inspiration, integration, intelligence and instigation, but Cathrin Schaefer, BeiGene's Head, Market Access Europe, identifies four value markers to rally around: clinical value, patient value, economic value and societal value. And, it is never too early to begin, she observes.

"Considerations regarding access should be integral to the design of clinical trials. Key responsibilities include anticipating inquiries not only from regulatory bodies like the FDA or EMA but also from HTA bodies or payer authorities. It's imperative to anticipate the evolving treatment landscape, recognizing that today's norms in care may shift over time. Planning for patient access should inform all discussions on clinical development, including clinical trial design, endpoint selection, comparator choices, and inclusion/exclusion criteria, in order to enhance reimbursement success. This is becoming increasingly important in light of the forthcoming EU Health Technology Assessment (HTA) process set to commence in 2025."

"The aim, therefore, is to meet the four dimensions of value – clinical, patient, economic, and access – as strongly as possible."

An 'early start' ethos requires agility to account for the myriad of fast-moving elements of health care systems across markets and geographies and Schaefer makes a key insight in stating: "Anticipating inquiries from various national systems well in advance is a critical success factor as it is meticulous planning for patient-related outcomes. These considerations should be seamlessly integrated into the trial design. Ultimately, the central goal is to demonstrate that a product contributes to bring additional value to healthcare system. Funds will be dedicated to products that provide extra value, whether it's through financial advantages, improving patient well-being, or adding to the overall good of society."

"The aim, therefore, is to robustly address the four dimensions of value – clinical, patient, economic and societal – as strongly as possible. Failing to meet any of these aspects means the product will likely not gain traction. Many excellent clinical studies have failed because they did not fulfill all four of these requirements."

Meeting them is an essential but every point needs to be infused with excellent communication so they can resonate across the value chain.

The early start mantra is echoed by Marc van Unen, Business Unit Head Cardiovascular of Bristol Myers Squibb, an experienced pharma business leader and launch expert, who feels existing industry core approaches still have validity and there is no need to invent a new launch lexicography or formulate a new range of processes.

“There is a lot of turmoil and businesses are really struggling to adapt but, whether you have a small product or a big product, the work is essentially the same, teasing out the brand benefit, creating a brand architecture, brand name, key message and sales aids. What is relevant for millions of patients is relevant for a 200-patient population,” he comments.

“It is about preparing the product, when to market it and preparing the company and, here, I would really focus on clarity of message about end benefit of a product and, ideally, describe that in a few words. That will help guide everything else.”

“It is essential to engage with the medical experts and key opinion leaders in the area.”

The imperative to translate product benefit into voices that can have impact at both scientific and commercial levels is echoed by Catarina Santos, Executive Director Medical Launch Region Europe at Novartis, who observes. “It is essential to engage with the medical experts and key opinion leaders in the area, who are often also the investigators in the clinical trials, so we can learn from their experience and understand, early on, their key needs and concerns, and those of the patients who will ultimately benefit from our medicines,” she said.



“Pre-launch noncommercial teams may begin mapping all the essential stakeholders as soon as feasible, building a strong scientific engagement plan, and gathering many layers of pertinent insights to inform launch strategy.

“Starting early seems to be a key factor for launch success however, many times, we start these processes and deploy resources quite late, constrained by the polarity of short-term revenue versus mid-term pre-launch impact”

The unifier throughout the entire product journey is the patient. And communicating to them via HCPs, patient groups or general condition awareness projects is the oil that stops initiatives grinding and jarring.

Communication, both internal and external, is the binding agent of the process and developing a strong narrative around the science, efficacy and value comes early in the operation. Marc van Unen, the author of *The Product Launch Playbook*, adds: “What is critical is the thinking around the product profile. What is the real end benefit? What are the clinical endpoints and how can we translate that to a benefit for the patients, for the physician for their practice? Also, how do we see its potential to society. How can we show its value in terms of cost savings for the healthcare system?”

“All of this has to be done at the dawn of the product’s existence.”





Communicate to Elevate

The increased pressures are crystalized in a commentary by analyst firm Deloitte which highlights that one third of drug launches miss expectations: It states: “Today’s drug launches require manufacturers to have more resources, deeper clinical expertise, better cross-functional coordination, and greater agility.”⁴

The commentary further observes that launches are a window onto an organization’s health, adding: “Our interpretation is that as the market continues to evolve, companies’ traditional organizational structures and approaches have not kept pace.

“Through our analysis, we have concluded that a company’s overall performance is reflected in the way their drug launches perform. As such, companies have the opportunity to rethink their operating model, portfolio strategy, and research and development, as well as their ways of working and collaborating. Companies should think of their drug launch strategy as an organization-wide effort that involves all organizational functions and requires diligent planning and synchronized collaboration.”

“By engaging early, creating a compelling communication platform, and having a clear value proposition, launch teams can generate support for their product.”

Pre-launch planning is never an exercise in isolation and cross-departmental collaboration is essential. Communication is a ground zero basic but its importance is often overlooked or drowned in the weight of process.

Cathrin Schaefer views internal collaboration as a powerful component of launch success. She states: “I go back to the four dimensions of value, clinical, patient, economic and societal value, and it is critical to have very clear messages around these for both internal and external stakeholders.”

Catarina Santos believes good communication should be enshrined as part of a company’s culture for success. “Communication is absolutely key, and, in my opinion, this is more than having clear statements; it’s about being humble and accepting (and integrating) the inputs of the different roles, different departments, different geographies... Being curious and truly listening defines an organization’s culture,” she says.

“The power of asking questions and having an environment where questions can be raised, is immeasurable. In a pre-launch phase, as we are learning and course correcting, we need that strong cross-functional team, typically with very different expertise and understanding of the problems to be solved, to share a common goal: launch success! When there’s such a level of communication that everyone is tuned in, has a part to play in the shared external success, and the radars are pointed outwards, magic happens. Occasionally, the fight is lost internally.”

A study by the Centre for Executive Leadership for the Pharmaceutical Industry highlighted the imperative of building a strong communication platform to empower corporate teams to establish relationships with key stakeholders.⁵

It states: “By engaging early, creating a compelling communication platform, and having a clear value proposition, launch teams can generate support for their product.”

The study advocates a culture of continuous learning and improvement to maximise launch potential in the current, unpredictable commercial climate.

Language and tone clearly need attention and refinement and Cathrin Schaefer cautions that it can be easy to fall into common usage and terminology. She explains: “The term ‘unmet medical need’ is sometimes applied by the pharmaceutical industry in instances where it may not be entirely accurate, leading to an overuse of the phrase.”

“True comprehension only comes from delving into the patient’s journey within the clinical pathway. It’s through this understanding that one can discern whether a genuine unmet need exists.”



Clarity is Power

Companies can be awash with a soup of data, knowledge and information at launch which can clog up communication channels ranging through internal liaison, preparing scripts for customer facing teams, connecting at health and digital summits and congresses, and engaging with HCPs and patients.

Numerous pieces of research also underline communication's pivotal role in helping prescribers understand and use novel medicines. The studies emphasize the value of clear, consistent messaging at all points of the product and patient journey with life sciences insight platform

Within3 framing the importance for customer facing teams in the statement: "Before, during and after the launch, *customer facing teams* should get a clear communication cadence that educates, motivates, and sustains a commitment to the product. By establishing a pre- and post-launch communication plan, stakeholders will have access to the same information and a better understanding of the product's goals. Clear, consistent messaging creates more confident ambassadors for a new product."⁶

"Before, during, and after the launch, customer-facing teams should get a clear communication cadence that educates, motivates, and sustains a commitment to the product."

The message from speaker platforms needs to be established in pre-launch and remain aligned and consistent with what stakeholders are hearing in their 1:1 engagements and reading in the media.



Embrace Experience: Good and Bad

A forensic assessment of the knowledge in an organization along with an appraisal of where data, evidence and sector experience might be missing are vital in pre-launch and Catarina Santos advocates an honest approach to illuminate both expertise and deficiencies.

“We need to assess how much knowledge we have in-house and what is happening in the market. Are we launching a drug in a space that we already know? Is previous knowledge an asset or a liability?” she asks.

“Knowledge is key and the more granular the better.”

“By being open we can reduce volatility and identify problems much earlier. It is vital market intelligence that should not be overlooked.”

“Knowledge is key and the more granular the better. Previous launch experience is important as well as knowledge in the therapeutical area, as they both accelerate learning, but there is a danger of overestimating our market knowledge and that can have a blinding effect. It can create a climate where questions aren’t asked, and preparations start too late.

“Cycles of change in healthcare are becoming quite short and reassessing our knowledge on the current marketplace is key. The recent pandemic, for example, shaped the health care system significantly and so, having the openness to defy our assumptions and get knowledge from different sources is a really important element of your approach.”

Duncan Trew further advocates for an open culture that draws in experience from previous sector launches and expertise from other areas and, for maximum benefit, this needs to consider historical company misfires and failures as well as current optimism.

“It is not about critiquing other people’s work or being negative; it is utilizing everything you have in preparing for launch.”

“We should also look back occasionally at what didn’t work so well in the past and learn from it. But sometimes there is a reluctance,” he says. “I understand that teams are excited, motivated and in acceleration mode but there may be people still in the company that worked in the area five or ten years ago who have some relevant information. Let’s bring them in and listen. If there are painful lessons, we should learn from them.

“These experts could include personnel from different therapeutic areas who will often spot important points that teams have not even considered. It is not about critiquing other people’s work or being negative; it is utilizing everything you have in preparing for launch.

“By being open we can reduce volatility and identify problems much earlier. It is vital market intelligence that should not be overlooked.”



Control the Message

With new horizons of therapy and AI influence comes extra regulations and Cathrin Schaefer cautions that new FDA legislative proposals and the reform of EU pharmaceutical legislation requiring an extra EUHTA (JCA) dossier from 2025, will add more complexity.

“There will be many more mandatory requirements around health economic evidence which will be challenging to address, especially for small and medium enterprises ” she says. “This only heightens the need for a sharp focus during the pre-launch period.

Marc van Unen states, “The margins for error are getting smaller and the consequences greater if you do not get this phase right. If you don’t have all your evidence and market research detailed with clarity then you can run into a wall when it comes to reimbursement negotiations.”

Being ‘on message’ is never more important than at this phase and clear communication through engagements, internally and externally, will pay dividends in both effective delivery and understanding, and being able to respond, to nuanced needs within markets.

Van Unen continues: “Start interacting with payers and key clinicians and communities and develop a good idea of what they want through insightful questioning and then you can really build the brand. This is market preparation.

“A key factor is this global-local relationship where the knowledge that sits with global can be transferred from head office to local regions and affiliates who, after all, have to generate sales. Preparing the company to manufacture the product and distribute it is a complex undertaking and a lot of launches fail because of basics like a lack of product supply or they don’t generate enough awareness in a crowded market. That happens when you haven’t really controlled your message.”

He believes that sharing expertise across global and local networks combined with establishing open and transparent lines of communication across cross-functional teams are the pillars of a platform that showcases product, content, brand and value, and helps organizations withstand negative external market forces.

Catarina Santos favors pauses along what can be a hard-charging journey where teams are in full speed into internal checkpoints and regulatory landmarks. “This is a subtle point that can be quite challenging,” she concedes. “There is a natural confidence in the product, and everyone is moving forward so it is difficult to have those moments, but the launch excellence culture is fundamentally based on openness to receive feedback, pause to evaluate, and course correction whenever needed.

“Creating a unique launch culture is sometimes overlooked. Planning and execution are crucial, of course, but equally crucial to the launch process are fostering a strong cross-functionality and accountability and maintaining a culture of openness and learning from the outside world.

“This pre-launch culture is sometimes different from the pharma business as usual, but it can have a positive impact.”

Throughout pre-launch, and beyond, communication is a prime asset. It unites preparations, harnesses knowledge, strengthens brand purpose and minimizes the risk of misfiring. Having clear messages that resonate, can be shared easily and targeted effectively help ensure a product’s evidential and commercial firepower are fulfilled.

“Launch excellence culture is fundamentally based on openness to receive feedback, pausing to evaluate, and course correction whenever needed.”

Innovator and oncology medical strategy specialist Dr Douglas Yau, who has more than 20 years high level experiences at the biosciences frontline, holds communication as a key sacrament of multi-faceted pharmaceutical launches through the mantra: “Develop a Comprehensive Medical Communication Plan. Create a robust plan for disseminating scientific and clinical data through channels such as medical congresses, peer-reviewed publications, and digital platforms.”



Conclusion

Launch tasks are intense and immense, particularly when working at the onset of a three-year timetable, but good communication empowers a potent medical affairs strategy and builds key relationships through assembling teams, medical landscape analysis, education and support.

Launching a product is a complex, multi-faceted operation with ever-present potential for product messages to land awkwardly without full understanding and reduced impact. Crystalizing the knowledge, experience and expertise clearly and succinct messages that have meaning across the patient and product journey can boost success and pay dividends.

Clearer communication is a gateway to clinical success and commercial return, brand reputation and delivering on an organization's fundamental purpose to change people's lives.

"We work on a compound for such a long time before it enters the market which can be challenging but getting a product to patients is a fantastic and uplifting thing to do," adds Cathrin Schaefer.

"Making a difference to patients who are suffering from a chronic or life-threatening disease is inspiring and, at times, it is difficult to understand fully what that means for them but that is something we should focus on and hold on to throughout our endeavors."

Catarina Santos adds: "It is super rewarding, and it is what we really bring to the marketplace. Every successful launch makes for a stronger healthcare system. We are building something with our teams and external stakeholders that provides solutions for patients; the lasting imprint is that health care professionals can then diagnose faster and have more options to treat their patients and achieve better outcomes."

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Ten Keys to Pre-Launch Success

- 1 Start Early
- 2 Assess Knowledge from Multiple Sources
- 3 Invest in Understanding & Learning
- 4 Engage with Stakeholders at a Deep Level
- 5 Research All Aspects
- 6 Be Flexible and Adaptable
- 7 Create a Collaborative Culture
- 8 Prioritise Great Internal and External Communications
- 9 Go Global & Local (ensure it feels locally relevant)
- 10 Digital and AI can enhance the thinking and strategy. Embrace and Use it!





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The views of the contributors are their own.

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About 60 Seconds

60 Seconds is a remote coaching app designed to help users communicate with greater clarity through practice, coaching and measurement. It was built by a coach for coaches to deliver measurable learning momentum.

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