

Achieving Launch Excellence In The Challenging Healthcare Markets Of Today

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In partnership with





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INTRODUCTION: COMPETITIVE AND COMPLEX MARKETS

As 2018 draws to a close, it's clear healthcare markets are becoming more competitive than ever before.

Several factors are driving this. The increase in research and development (R&D) spend, which is seen across the board, is leading to rising levels of innovation and a higher number of approvals for new medicines. Additionally, the growth in annual healthcare spend is also expected to surge at an annual rate of 4.1% from now until 2021; this is triple the amount spent between 2012 and 2016.¹ More generics will make it difficult to demonstrate value, with patents ending for \$190bn worth of products in the same period. Each of these elements will result in more products flooding already crowded markets.

At the same time, healthcare markets are becoming more complex. Central to this is a growing ecosystem of stakeholders with different needs, challenges and pain points. These stakeholder groups are interconnected and becoming more active across digital channels and technologies. To add to this complexity, the channels these stakeholders are using continue to evolve and proliferate. 'Key to this success is transforming both the operating models and approaches to brand planning taken by pharma and biotech organisations'.

¹'2018 Global health care outlook: The evolution of smart health care', Deloitte



R&D Spend In US Dollars

Source: https://www.statista.com/statistics/309466/global-r-and-d-expenditure-for-pharmaceuticals/

As a result, planning a launch is more difficult and more complicated. The bar has been raised for launch success and launch excellence is now more critical than ever.

To find commercial success in this hypercompetitive era, the pharma industry needs to look beyond the patient experience and take a more holistic view, orienting around the needs of the broader market - from payers to regulators, prescribers and key opinion leaders (KOLs), and of course the patients themselves.



Key to this success is transforming both the operating models and approaches to brand planning taken by pharma and biotech organisations.

<u>Blue Latitude Health</u>, a global consultancy with expertise in pharma and life sciences launches, and Informa's Pharma Intelligence have produced this guide to launch excellence for modern healthcare.

This publication was born out of industry research amongst pharma executives from various countries. The research was conducted between August and October 2018 and included a quantitative survey completed by more than 100 respondents: 'How are the commercial dynamics of launching a brand or portfolio changing', as well as qualitative interviews with pharmaceutical leaders. It draws on Blue Latitude Health and Pharma Intelligence's extensive expertise and knowledge in this area.

Here we set out recommendations for brands, portfolios and organisations committed to achieving launch excellence.

TRANSFORMING THE OPERATING MODEL

Pharmaceutical and biotech companies have traditionally organised themselves as 'product-centric organisations' – a model of internal focus which leverages the existing skills and capabilities of the organisation to develop the best possible product.

This model has succeeded in the past when used in less competitive markets. However, in hypercompetitive markets, where the big unmet needs have been filled and many products are already available, it's time to transition to a new approach.

A more responsive and more market-oriented model is key to launch success as it focuses on developing not just the best product, but the solution. This means developing a holistic approach to solving customers' problems, which unites products and services and is based on a firm foundation of understanding customer needs and the market. It enables the organisation to quickly adapt to changing market conditions and ensures the solution is still relevant at launch.

What does a market-orientated model look like in reality?

Our research identified three key areas for achieving a market-oriented operating model for launch excellence:

1) Apply commercial thinking earlier

Applying a commercial lens to the asset early enough helps teams make tough decisions about the drug and shape the data generation strategy to ensure the outcomes meet specific market needs.

This requires commercial teams to anticipate how the market will evolve and understand the changing environment throughout the launch period. To achieve this the commercial team needs to collaborate earlier in the process, anticipating the patient pathways, the prevailing standard of care and any unmet needs which remain. This



'It's crucial to develop a more responsive and more market-oriented model which focuses on developing not just the best product, but the solution'.



view of the launch environment informs the target product and commercial profiles, as well as associated evidence generation plans.

Mike Yates, Senior Pharmaceutical Executive, agrees that the product teams should be formed earlier. He says: 'I would put in place whoever's commercially accountable for the brand needs before the phase three is signed off. When you start building your phase three, your core programme, you've got to have the teams which will actually be accountable for launching and delivering value for the product'.

Rich Statham, Vice President, Specialty and Oncology Business Lead, Otsuka Europe, contextualises further, explaining: 'The commercial group needs to work closely with the clinical team to ensure they are delivering against the needs and challenges of key markets ... It is also essential to form cross-functional teams as early as possible so they can shape the clinical development to ensure the best chance of a successful launch'.

Feeding this attitude into the research and development (R&D) of the product is also important. R&D teams are frequently incentivised to optimise trial efficiency. Whilst this can reduce time to market and optimise the bottom line, replicating trial protocols without a view of the future market may result in missed opportunities and in turn detract from the top line. This means R&D incentives must be re-aligned, and a culture of collaboration encouraged, along with establishing the appropriate governance structures.

'We're seeing the time to get to market shortening and there's pressure on regulators and market access to assess things quicker. Everything is speeding up', says **Alex Blyth, CEO of LifT BioSciences.** 'Having all your ducks in a row and a very seamless strategy for the launch across multi-parts of the organisation, from manufacturing and supply to clinical, market access and marketing strategy, is now more important than ever. It has to be seamless because otherwise you're delaying your time to launch unnecessarily. People need to learn to run faster and be more organised to run faster'.

Whilst the R&D team needs to think more commercially, the commercial team will also have to be empowered, enabled and willing to make decisive go, no-go decisions earlier on.

These tough decisions are a result of growing pharma portfolios and smaller and more frequent launches, which reduce the amount of resource available for each launch. To counter this, pharma needs to prioritise resources more effectively and shift resources to drug candidates which have the highest likelihood of success, as soon as the data signals outcomes.

Crucially, commercial teams have to take a brutally objective view of the asset to assess its future market potential – a task which may be emotionally challenging for an R&D team which has spent years on developing a compound.



'The commercial group needs to work closely with the clinical team to ensure they are delivering against the needs and challenges of key markets'. – Rich Statham



'People need to learn to run faster and be more organised to run faster'.

- Alex Blyth



One **Associate Director of Global Commercial Strategy** explains: 'It's critical to kill non-efficacious drugs early on because the bar is very high. You have got to keep outcomes in mind in early stage – as early as phase two. You can't leave that to phase three because then you never get reimbursed. It's very easy to demonstrate high signal and proof of concept. As the clinical trials get more complicated and cumbersome, the efficacy signal measurement decreases in phase two and it's even less in phase three. So, kill the non-efficacious drugs early on; make those hard decisions'.

2) Align internally so you can align externally

Prescription and reimbursement decisions are ever-more influenced by broad and interconnected stakeholder networks, creating an increasingly complex external environment for pharma to navigate when preparing for launch. At a minimum, these stakeholders can include regulators, payers, health technology appraisers, patients, their caregivers and support groups, KOLs, prescribers and nurses.

The responsibility for understanding and communicating with this diverse range of stakeholders also lies across different functions, at different times, during the launch planning process.

It makes sense for these teams to align, ensuring the delivery of a coherent strategy and consistent communication in the run-up to and at launch. However, our research shows that organisations often struggle to foster this collaborative culture.

Collaboration should start from the moment launch teams are formed at a global level and it must persist as recruitment expands horizontally across functions and vertically through regions and into markets.

Function, region and market leaders should be brought together regularly and given the opportunity to shape the strategic direction for the brand. This ensures emotional buy-in to the strategy from global to local teams. Launch teams can then incorporate the market-specific nuances which will enable rapid access and uptake and the ability to track launch readiness.



'Kill the non-efficacious drugs early on; make those hard decisions'.
Associate Director, Global Commercial Strategy



Major Barriers To Achieving Launch Success



Respondents identified four common barriers to achieving launch success with degree of competition and internal alignment rated as the most significant

'If you've got everyone singing from the same hymn sheet and there is a lack of alignment somewhere, you can very quickly diagnose why it's not working and you can do something about it', says Daniel Shomer, Marketing Excellence Manager, Commercial Operations, Otsuka Europe. 'If companies act quickly they can change that launch trajectory but it's very difficult to do that if you've got lots and lots of different strategies and tactics going on'.

There is a need for absolute clarity and alignment on the problem the product is trying to solve, first internally and then externally', agrees Yates.

Using external suppliers to facilitate difficult conversations in collaborative, crossfunctional meetings and key touchpoints can maintain objectivity and ease the path to alignment. Supporting tools such as launch readiness trackers, key activity roadmaps and insight-consolidating market-shaping guidebooks all help to keep teams aligned and progress on track.

'Otsuka provides a great example of this approach to collaboration, with disease area teams set up regionally and linking to the company's regional disease area strategy teams, which are made up of three core functional leads [marketing, medical and market access] and members from Europe working closely with a country representative from each of its major markets', explains Statham.



3) Increase organisational responsiveness

In hypercompetitive markets, customer needs are constantly evolving as the launch of new products and services change the experiences and expectations of patients, physicians and other key stakeholders.

Market-oriented pharma and biotech firms react quickly to new insights and incorporate these learnings rapidly into launch plans. However, our research shows that whilst organisations perform strongly when discovering fresh insight, the majority are not well-equipped to pivot quickly and incorporate these fresh insights into planning.

A well-managed collaborative decision-making process is an important step towards empowering teams to respond efficiently and effectively to market changes. Without this, meetings and ideas burden the organisation, reducing its ability to move fast and be agile. 'The majority of organisations are not well equipped to pivot quickly and incorporate these fresh insights into planning'.

Perceived Organisational Performance: Select Capabilities

Please rate how well your organisation performs across the following capabilities? (with 1 being 'Not at all effective' and 5 being 'Very effective')



Respondents rate their organisations most positively with regard to developing deep market insight (68% top-two box¹), incorporating insights into planning (65% top-two box¹), and executing launches in a timely manner (63% top-two box¹). They provide the lowest ratings for scenario planning for uncertainty (46% top-two box¹), reacting quickly to new insight (48% top-two box¹), and appropriate resourcing (49% top-two box¹).

Base: All respondents (n = 101). 'top-two box: 5 Very effective & 4 scores / 2Bottom-two box: 2 Not at all effective



Collaborative decision-making models must be well-managed to empower teams and respond efficiently and effectively to market changes. However, the key question then becomes: how can the organisation be more agile whilst at the same time become more collaborative?

Scenario planning is a useful tool for maximising responsiveness and informing decision-making. Firms can identify and prioritise the critical market assumptions, insights and uncertainties and use them to build detailed maps of potential futures at or beyond launch. Launch strategies can then be designed, where possible, to succeed in any future outcome and contingencies can be developed according to the prioritised risks and uncertainties of each scenario. Each situation requires a roadmap of sign posts which, when monitored frequently, provide a 'scenario outcome' early warning system which commercial teams can use to make decisions.

Avoiding an annual strategy and instead setting and adopting quarterly, or monthly 'light touch' planning cycles is another tip for helping teams focus on planningassumption validation.

Key internal and external performance indicators can help to identify market changes and fresh insights which can be rapidly incorporated into strategy.

Full team quarterly meetings should be interspersed with these light touch cycles which are led by a small steering committee of cross-functional, region and market leads who have authorisation to pivot the launch strategy and a governance process for disseminating plan updates to the full team.

Blyth agrees, emphasising the need for good governance and accountability structures. He explains: 'Agility requires very clear lines of responsibility as to who is going to make what decision in which scenario. If everything comes down to large-scale committees, I don't think you can be really agile'.

An example of this working well can be seen at Roche, which has adopted quarterly planning and relays feedback regularly from the field force to understand performance drivers and make rapid adjustments.

RE-FOCUS BRAND PLANNING

Never before has the statement 'you only have one opportunity to get a launch right' been as true as it is in hypercompetitive markets with complex stakeholder relationships and influences.

Whilst the breadth of choice available to patients and healthcare professionals (HCPs) is a good thing, it makes standing out from the crowd a formidable task for anything less than a revolutionary innovation.

Competing pharma companies are vying aggressively for a share of mind and voice. However, they are also required to communicate increasingly complex, integrated value propositions which outline the clinical, economic and societal benefits of the brand, to an increasingly networked stakeholder group. As a result, HCPs are facing information overload.



'Roche has adopted quarterly planning and relays feedback regularly from the field force to understand performance drivers and make rapid adjustments'.



Our research has identified four key principles for optimising the brand strategy which, when well-executed, will help the next generation of healthcare brands achieve launch excellence.

1) Focus on the patient sub-segment experience

Clear patient identification is critical to the success of any brand; however, in hypercompetitive markets launch teams need to be even more specific about who they're targeting and the customer's unmet needs. This can mean making hard trade-offs about who the brand is for and crucially *not* for in order to align around a specific sub-segment.

A launch will only be very successful if it has truly met a previously unmet need, according to one **Associate Director of Global Commercial Strategy**: 'A launch excellence framework should help you uncover the market needs and understand the market definition, because you may want to conquer the world with a new drug, but you have to ascertain if targeting everyone is really the right thing to do'.

Tightly defining the target segment enables you to identify the patients who will have the best response to your brand and ensures you understand their truly unmet needs, challenges and pain points. Then, you can address these needs with targeted, highly relevant support services.

Along with patient profiles, precision tools such as biomarkers and companion diagnostics can help HCPs to identify the right patients at launch, simplifying the prescribing decision and maximising the benefit to the patient.

Yates emphasises the value of using a bell curve model to aid the patient stratification process. He says: 'Once the top responders have been identified, you can work backwards down the bell curve looking for opportunities to enhance the patient experience as you move further from those who receive the greatest benefit'.



'You may want to conquer the world with a new drug, but you have to ascertain if targeting everyone is really the right thing to do'.

 Associate Director of Global Commercial Strategy





This approach ensures patients and physicians receive the best possible experience from the outset, increasingly the likelihood of peer-to-peer referrals which can accelerate launch uptake.

2) Build a standout value story

Creating clarity around the value story is an essential aspect of product launch excellence, especially in hypercompetitive and complex markets where your stakeholders and customers are flooded with information. 'You must be able to communicate incremental or differential benefits over the current standard of care. In hypercompetitive markets, a me-too perception is just not good enough. Something which is "as good as" just won't get funded', reveals **Statham**.

Novartis provides an excellent example of how the early application of a commercial lens can set up a brand's value proposition for maximum impact. The pivotal studies CLEAR and CLARITY successfully established psoriasis product Cosentyx (secukinumab) as superior to AbbVie's market incumbent Humira (adalimumab).

In an interview with *Scrip* in August, *Novartis Pharmaceuticals CEO Paul Hudson* said that Cosentyx was 'a market leader on new patients with psoriasis. We are ahead of all the new launch competition and we are also the market leader in rheumatology', he explained, illustrating the success Cosentyx has achieved.

Novartis' success hinged on identifying key insights about treatment goals early and shaping the studies to perfectly align with the brand's value proposition at launch.

Shomer refers to this as the 'golden thread' of insight. 'The challenge is that a lot of companies don't always have good insight processes in place. And if they do, how do they make sure that the insight is anchored and pulled through? You need to ensure this golden thread runs right the way through your strategic planning into execution. If you get that right I think you can see a lot of success with a launched product'.

It's critical to lay the foundations of the value story as early as possible in the planning process to maximise the benefit achieved at launch.

Developing treatment journeys at a sub-segment level provides a tool for teasing highly specific patient needs and insights. These journeys help teams to visualise behaviour, frictions and barriers, and pain points at each stage of the disease. They also illustrate the gaps which prevent the best outcomes, as well as the opportunities for an innovative launch approach.

Once the journey and insight has been developed, cross-functional teams then need to align around the *ideal* proposition at launch and work backwards to identify the product data and company services which are required to give credibility to the claim.

It's important to pressure test the proposition using competitor simulations to ensure the market insights and brand benefits will remain advantageous at launch.



'The golden thread of insight runs right the way through your strategic planning into execution'. – Daniel Shomer



Once the target proposition has been defined, all pre-launch market-shaping efforts across the different functions should be aligned to the proposition and all external communications refined to align with specific stakeholder communication preferences.

If the organisation is successful, target stakeholders will quickly understand the value brought by the brand for specific types of patients at launch.

3) Build early KOL endorsement

To maximise launch uptake in a hypercompetitive environment, stakeholders should be waiting to prescribe the brand as soon as it hits the market. Whilst it is critical to generate awareness and excitement in the scientific community for any brand ahead of launch, early KOL endorsement was identified in our research as the most important factor for achieving launch success in hypercompetitive markets.

Most Important Metrics During Pre-Launch Preparations



One **Commercial Director of Oncology and Haematology** goes on to say: 'Launch excellence means getting a high level of endorsement by ensuring key stakeholders are excited about the product we launch. A big part of this is generating awareness and ensuring experience with leading physicians/KOLs, which can be achieved through early and broad involvement in the clinical trial setting'.

An example of this can be seen in the early launch planning of Erleada (apalutamide). Janssen developed a broad, well-structured clinical trial program, combining companysponsored and collaborative trials, which is not only generating highly relevant patient data, it is also pioneering new primary endpoints with the endorsement of leading physicians. This comprehensive program is at the same time increasing physician experience and wide anticipation for the product amongst peers. For the first apalutamide indication Janssen has developed a well-coordinated scientific strategy which delivered the phase three data simultaneously to the pivotal trial readout at ASCO-GU and publication in the New England Journal of Medicine. This helped ensure apalutamide also achieved excellent levels of awareness and endorsement throughout the prostate cancer scientific community.



4) Engage with precision

HCPs are and will continue to be exposed to ever-increasing amounts of data from diverse sources of information. Companies must find efficient and effective ways to cut through the competitor noise, maximising the impact of resources available to them.

However, pharma launches are experiencing a reduction in resources and this means more emphasis will need to be placed on effective engagement planning.

Fred Bassett, Head of Strategy, Blue Latitude Health, explains: 'Whilst the "omni-channel" approach is superficially attractive, it can lead to situations where engagement is unfocused, with too many channels being utilised at sub-optimal investment levels. Effective planning in resource-constrained environments demands a focus on optimising priority channels and tactics at specific moments'.

By using learning journey models, companies can map the different stages of brand adoption and tease out key prescriber insights, pain points, information needs and sources across each step the customer takes. This identifies critical areas of intervention and the communication required to affect behaviour change.

Companies can use this information alongside the patient journey as a basis for developing a compelling, insight-rich brand or portfolio narrative which can be delivered precisely when the content is needed.

Collaboration between the medical and commercial teams at an early stage helps to achieve alignment on the target (tightly defined) stakeholders and the priority areas of communication. Teams then need to build precise engagement plans which incorporate marketing automation techniques in order to optimise every customer touchpoint in the run up to, and at, launch.



'Whilst the "omnichannel" approach is superficially attractive, it can lead to situations where engagement is unfocused, with too many channels being utilised at sub-optimal investment levels'. – Fred Bassett



KEYTRUDA CASE STUDY: THE TOP LAUNCH OF THE DECADE

Survey respondents highlighted Merck's oncology product Keytruda (pembrolizumab) as a standout launch of the decade.

Keytruda launched in direct competition with Bristol Myers Squibb's Opdivo (nivolumab). Both were highly effective lung cancer immunotherapies. However, whilst the launch strategy for Opdivo was based on addressing a broad patient population, Merck chose to focus on a newly diagnosed form of lung cancer with a commercial opportunity of up to \$8bn. Whilst this decision may have at first seemed conservative, the biomarker indicated that Keytruda would be highly effective in this specific patient population.

In the smaller sub-segment, Keytruda's value proposition of improved progression-free survival, combined with high response rates in comparison with the standard chemotherapy and few adverse events, showed the power of the product. However, the trial results for Opdivo showed little benefit for this group of patients. As a result, the difference between the two drugs became stark. Merck said in the summer that Keytruda was 'capturing two-thirds of new first- and second-line lung cancer patients in the US – a 20% increase in share since April – helping the PD-1 inhibitor power past Bristol-Myers Squibb Co.'s competing Opdivo (nivolumab) in the second quarter'. Additionally, Keytruda's second-quarter sales were \$1.67bn, compared with Opdivo's \$1.63bn, proving that a targeted approach can be the key to beating the competition.

In the US, about 60% to 65% of Keytruda sales derive from lung cancer, 15% from melanoma, 5% in bladder, 5% in microsatellite instability-high cancer, and the rest from all other indications (Scrip 29 July, 2018).

Merck has just announced that Keytruda, when used in combination with Pfizer's Inlyta (axitinib), is breaking new ground in first-line advanced/metastatic renal cell carcinoma. An interim analysis has revealed statistically significant and clinically meaningful improvements in OS and PFS, compared to sunitinib monotherapy, with the Keytruda plus Inlyta combination, Filings are planned (Scrip 18 Oct, 2018).



Standout Pharma Launch (Last 3 Years)



When asked to freely mention the standout pharma brand launch of the last three years, no single brand emerged as particularly dominant. Rather, a wide array of brands was mentioned, most commonly KEYTRUDA (15%), followed by OCREVUS (7%), HEMLIBRA (4%) and Darzalex (3%).



CONCLUSION: INCREASE YOUR MARKET ORIENTATION TO ACHIEVE LAUNCH EXCELLENCE IN THE CHALLENGING HEALTHCARE MARKETS OF TODAY

To achieve launch excellence in today's hypercompetitive and complex healthcare markets companies must transform, moving from product-centric selling models to becoming market-oriented organisations.

This means making changes internally as well as developing the brand strategy. Commercial teams should be engaged earlier and enabled to shape pivotal studies. Launch teams should work collaboratively, horizontally across functions and vertically across altitudes – from global through local.

Companies must also become more responsive by implementing a nimbler planning approach. For complex launches in hypercompetitive markets, strategies increasingly need to focus on the patient sub-population experience and brand teams must also crystallise the value story, pulling the 'golden thread' of insight right through strategy into execution.

Finally, to cement success, teams should build earlier endorsement with KOLs and engage customers with precision in order to cut through the noise and stand out in the crowd.

<u>Blue Latitude Health</u> has extensive experience in pharmaceutical and biotech launches and has worked with the world's leading health brands since 2003. Contact <u>Jeremy.Poland@bluelatitude.com</u> to find out how we can help you achieve your launch goals, from initial insight right the way through to customer experience, strategy and creative execution.

RESEARCH METHODOLOGY

1) Quantitative Research

On July 13, 2018, Pharma Intelligence emailed invitations to its subscribers to participate in an online survey. By August 22, 2018, Informa Engage had received 101 completed surveys, and delivered the survey analysis. Only respondents who were involved in brand launches for their organisations qualified to participate in the survey.

2) Qualitative Research

Blue Latitude Health's Jeremy Poland, Senior Consultant, and Natasha Cowan, Senior Content Executive, undertook hour-long interviews on the telephone around the topic *'How are the commercial dynamics of launching a brand or portfolio changing today and in the future'* in August and September 2018.



The interviewees:



Alex Blyth, LIfT BioSciences



Daniel Shomer, Marketing Excellence Manager, Commercial Operations, Otsuka Europe



Speciality and Oncology Business Lead, Otsuka Europe



Mike Yates,





Associate Director, Global Commercial Strategy



Fred Bassett, Co-founder and Head of Strategy, Blue Latitude Health

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We thank the leaders for sharing their experiences and hope they inspire you as much as they inspired us. All opinions quoted in the report are those of the individuals and not of the organisation they work for.



Blue Latitude Health is a global consultancy, made for modern healthcare.

At Blue Latitude Health, we combine the commercial focus of a consultancy with the creative vision of an agency, to unlock the potential in products and services that save and transform lives. Our focus is the commercialisation of healthcare innovations including medicines, devices, technologies and services.

We have extensive, end-to-end experience of launching breakthrough brands and portfolios; helping our clients to map future customer and patient needs and develop and execute winning commercial strategies.

For more information about our approach to launch excellence contact Jeremy Poland, Senior Consultant (jeremy.poland@bluelatitude.com) or Sophie Berger, Senior Marketing Manager (sophie.berger@bluelatitude.com).

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