



Evolving the product launch paradigm

How to successfully manage a product launch
to maximise returns

November 2018

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Foreword

Welcome to the Deloitte report Evolving the product launch paradigm: How to successfully manage a product launch to maximise returns.

In the past, pharma companies used to invest significantly in both pre-launch and post-launch activities and enjoyed notable peak sales thereafter. Today, the pharmaceutical industry is at a crossroad with most companies experiencing a period of significant challenges and risks.

Successfully bringing a product to market has been increasingly difficult. Pricing has become more controlled - and value based - as healthcare costs have increased to an unsustainable level. Customers realise there is little product differentiation and the traditional sales rep based go-to-market model is struggling to effectively communicate the value proposition to more demanding and informed customers.

In this context, how should pharma companies allocate their reduced development and commercialisation budget to more effectively and efficiently prepare for and drive a fast trajectory to higher peak sales?

We expect successful future products to benefit from substantial investments between phase 2b and launch backed up by a risk mitigation strategy, and paired with a more cross-functional approach and efficient digitally-enabled go-to-market activities.

Pre-launch activities need to have a strong focus, including early engagement with customers to co-develop the product value proposition (aligning R&D, Medical and Commercial) while capturing insights to inform the commercialisation and access strategy.

Building an asset light (and asset right) customer-centric and digitally-enabled go-to-market model is essential. It means lowering operating costs and risks (lean approach), focusing on new channels that can deliver a better return and greater flexibility, and accessing innovation and external capabilities through partnerships.

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The good old days of pharma are gone

In the past, pharma companies used to invest significantly in both, pre-launch and post-launch activities and enjoyed notable peak sales thereafter. Significant development and commercialisation investments in phase¹ 2b and 3 were paired with an expensive field force based go-to-market strategy that mainly targeted physicians. Such an expensive model was sustained by high drug prices and a steep trajectory to peak sales.

Today, the pharmaceutical industry is at a crossroad with most companies experiencing a period of significant challenges and risks: increased competition, shorter time-in-market, declining reimbursement, expiring patents, and slow sales growth leading to declining profitability.

Pharma companies' expectation is to maintain / reduce cost while the regulatory environment becomes increasingly complex and R&D pipelines are harder to fill. Furthermore, pharma companies need to embrace technological developments and respond to pricing pressures caused by healthcare reforms and government austerity measures.

Pharma companies now face three main types of risk²:

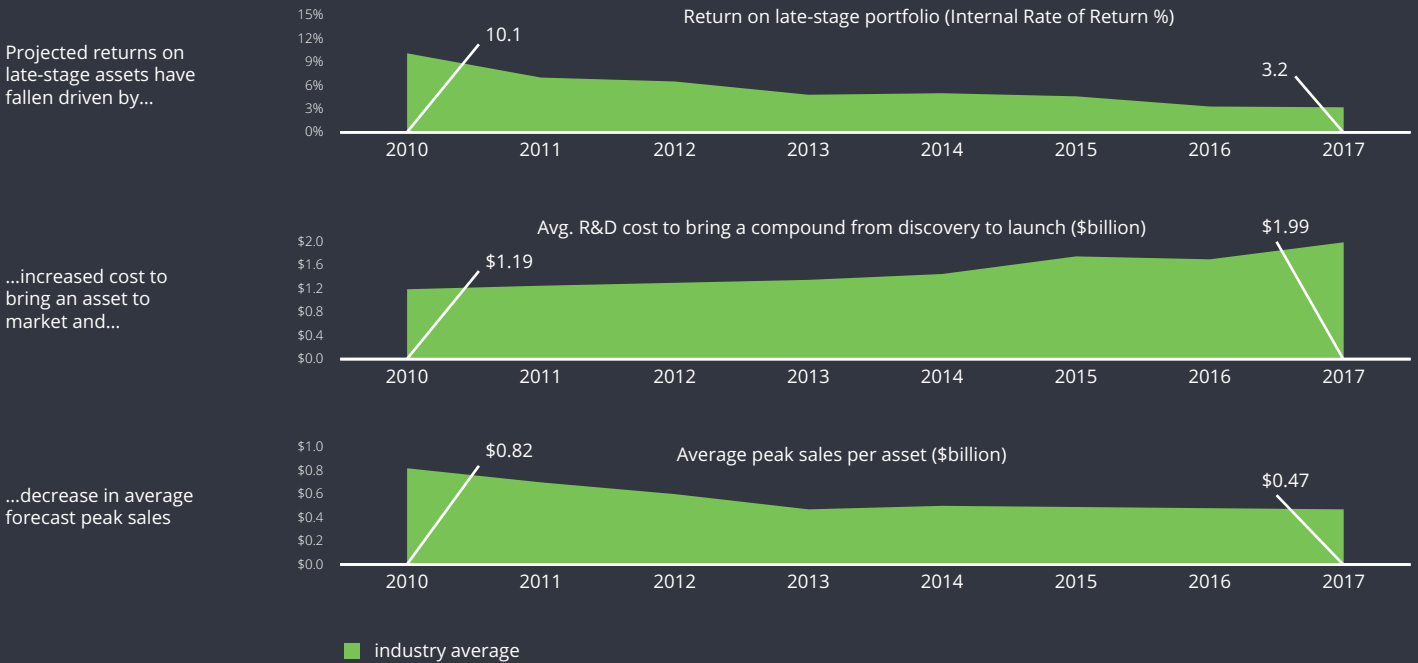
- **Scientific risks** – development requires time and new drugs need, on average, 12 years to move from the research laboratory to the patient. Only 0.1 percent of drugs that begin preclinical testing ever make it to human testing and 20 percent of those are approved for human usage³. Increased regulatory scrutiny is adding further layers of risk to the science of drug development.
- **Economic risks** – high failure rates contribute to lower investment returns. Therefore, high failure rates result in higher prices for those successful drugs. Higher prices, in turn, lead to increasing payer resistance to approve new products, further increasing the 'failure' rate to complete the vicious cycle.
- **Delivery risks** – gaining market access has become more difficult. Cost pressure is increasing and the necessity to prove that drugs deliver the promised value is higher than ever. Infrastructure to track and measure outcomes in countries such as the UK, France, Italy and some states in the USA adds complexity and drives costs, thus increasing delivery risks. Even when market access is granted after successful drug development, this does not guarantee remuneration for health care system participants. Too often, the expectations of good outcomes become elusive if patients do not comply with their prescriptions to treat chronic diseases. With the rise in double and triple combination treatments, it is virtually impossible to know which drug in the "treatment cocktail" is delivering the benefits and outcomes. As value-based-pricing increases, pharma companies need to become more involved in the overall delivery of treatments and definition of outcomes.

The last five to ten years have shown that successfully bringing a drug to market has been increasingly difficult. Pricing has become more controlled and value based as the healthcare costs have increased to an unsustainable level. Customers realise there is little product differentiation and the traditional sales rep based go-to-market model is struggling to effectively communicate the value proposition to more demanding and informed customers.

In a recent report⁴, Deloitte estimated the return on investment that a cohort of 12 large cap biopharma companies might expect from their late stage pipelines. Our analysis has shown a decline in the rate of return for the cohort from just over 10 percent in 2010 to under 4 percent in 2016 and 2017. The decline has been driven by an increased average cost to bring an asset to market, from \$1.2bn in 2010 to \$2.0bn in 2017, and a declining average peak sales per asset in the same period from \$820mn to \$470mn.



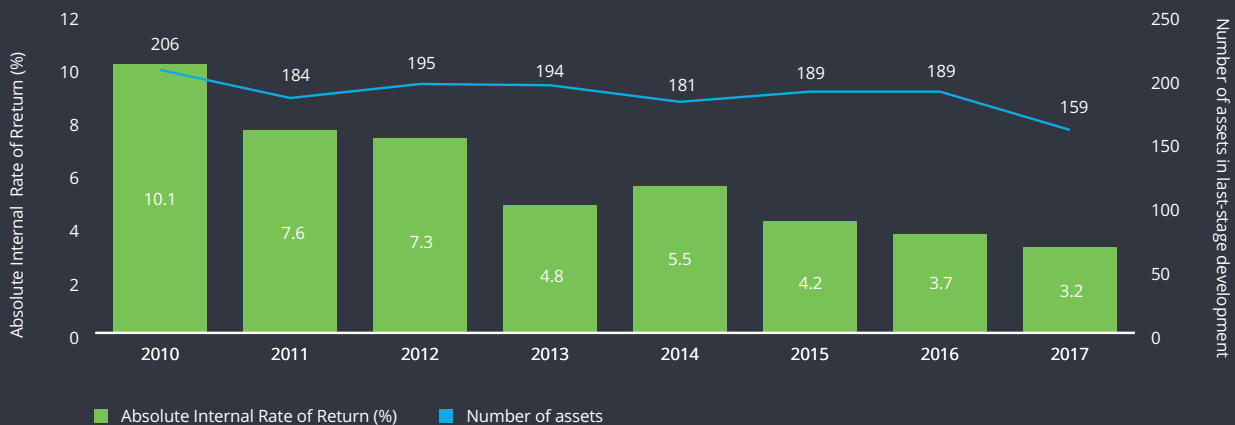
Figure 1. Return on late-stage portfolio (top), average R&D costs to launch (middle) and average peak sales (bottom) for cohort of 12 biopharma companies from 2010 to 2017



Source: Deloitte Centre for Health Solutions⁵

Furthermore, this cohort saw a sharp decrease in the number of late stage pipeline assets in the last year, which had remained fairly consistent over the previous seven years (206 in 2010 to 189 in 2016 and 159 in 2017 according to Figure 2).

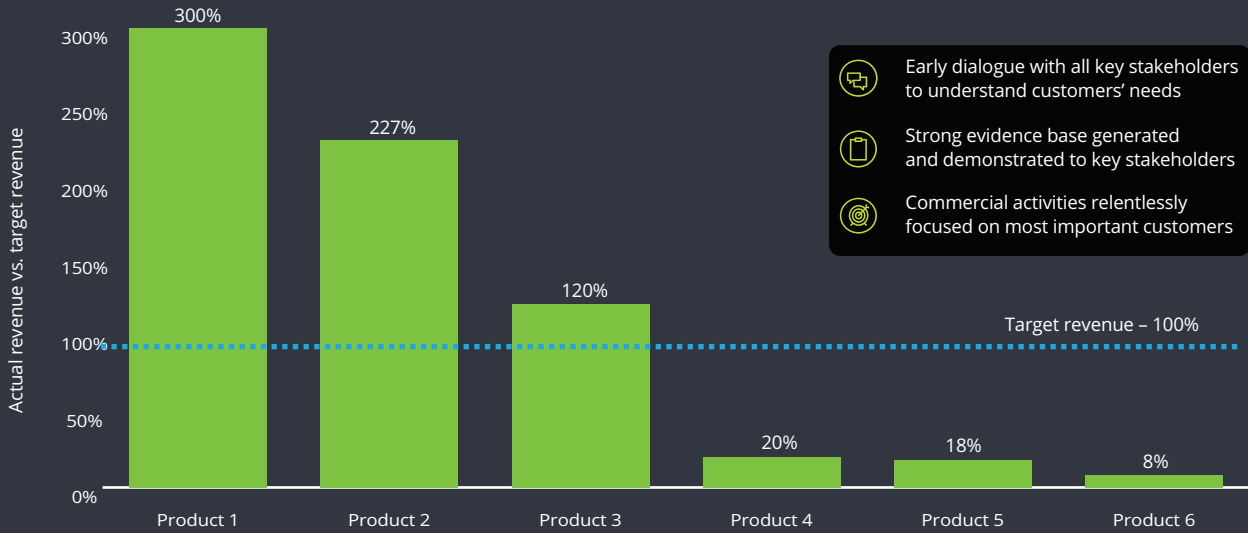
Figure 2. Number of assets in late stage portfolio



Source: Deloitte Centre for Health Solutions⁶

Developing and bringing an asset to market has become more risky and returns are by no means guaranteed, as a consequence, the available budget to develop and commercialise a drug is expected to shrink, requiring higher efficiency and effectiveness. Deloitte analysis shows that the traditional, fully integrated pipeline process from idea to R&D to commercialisation has been showing diminishing returns.

Figure 3. Actual vs. target revenues in successful and non-successful drug launches



Note: Products peak deviation between actual vs. targeted revenues have been analysed. Target revenues are based on initial analyst expectations shortly following the launch.

Source: Deloitte research⁷, 2018

So, how should pharma companies allocate their reduced development and commercialisation budget to more effectively and efficiently drive a fast trajectory to higher peak sales? Indeed, as the comparisons of some of the recent blockbuster-proclaimed drugs against their sales target shows, there have been strong launches by companies that adapt to recent budgetary constraints exceptionally well –we will dive into what they did right in the next section.

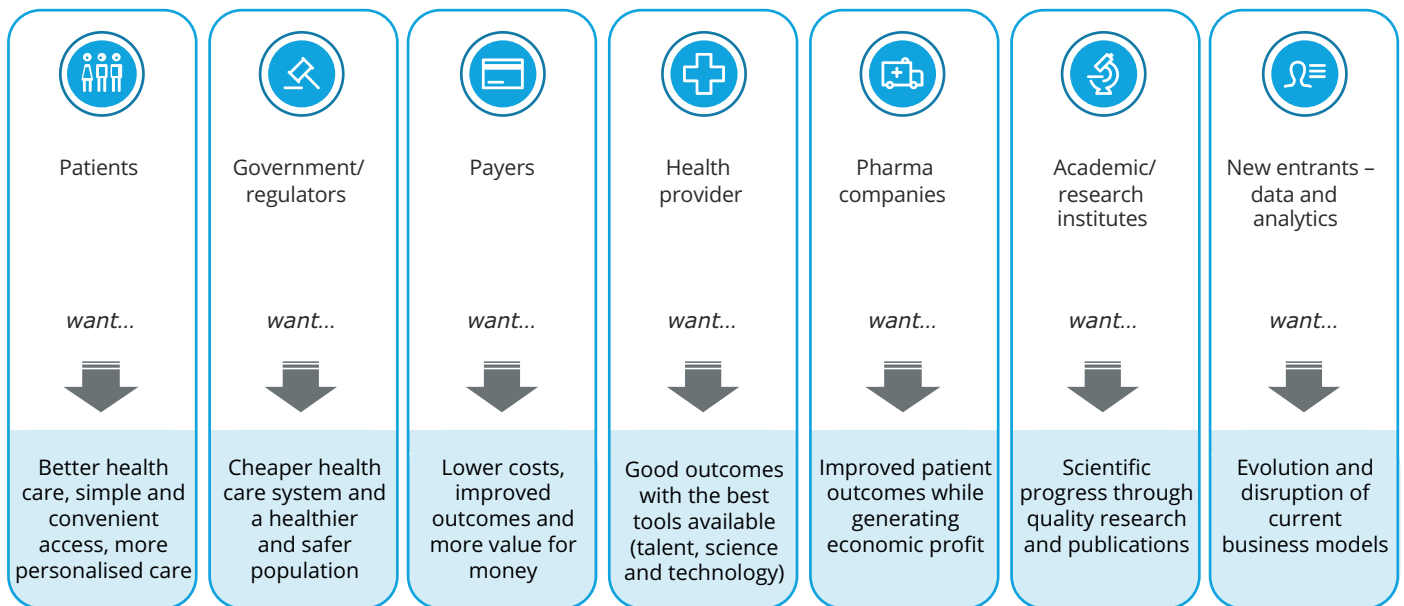


What's the deal?

Keeping these challenges in mind, companies are forced to review their current development and commercialisation approach. Strategies such as simply outsourcing a range of business functions and marketing or just tweaking the commercial model are not enough to succeed. The cross-functional collaboration becomes even more important: early alignment between Commercial and R&D allows a greater focus on patient needs; therefore streamlining the drug development and go-to-market process.

The many stakeholders in the healthcare ecosystem have different expectations: patients look for easier access to drugs while payers aim to lower the costs of medicines, and health providers seek to improve treatment outcomes. These expectations cannot be reconciled by marginal changes to how pharma operates. Instead, a new paradigm focusing on innovation and de-risking pharma is required if pharma is to achieve a greater success in the 21st Century.

Figure 4. Significant pharma challenges and opportunities are shaped by the different stakeholders and their needs in the health ecosystem



Source: Deloitte Centre for Health Solutions®

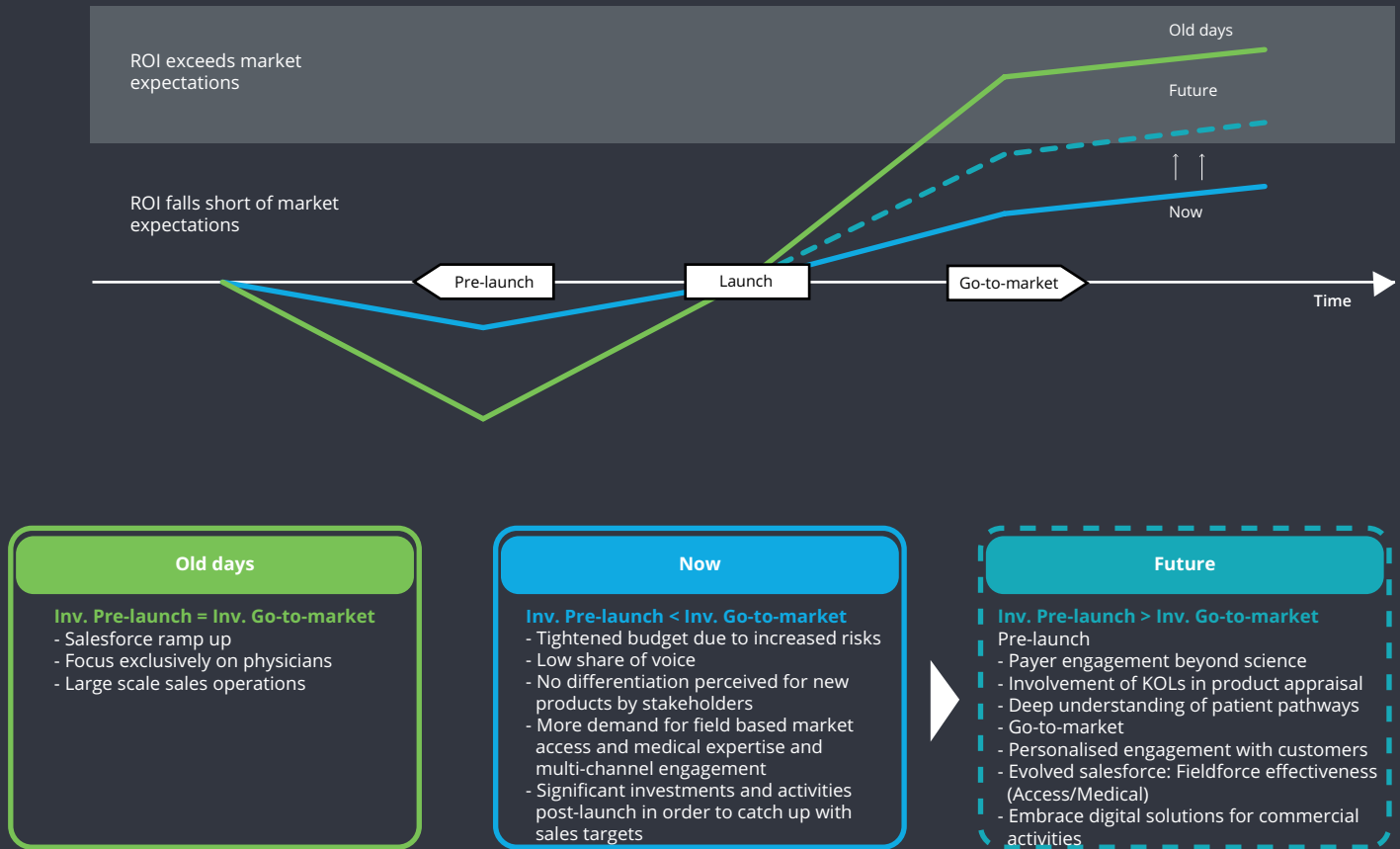
Given the limited budget available, should pharma companies focus their investment before or after launch? The future expects us to be more agile and multichannel.

We expect successful future drugs to benefit from substantial investments between phase 2b and launch backed up by a risk mitigation strategy, and paired with a more integrated, cross-functional approach (R&D and Commercial) and efficient digitally-enabled go-to-market activities.

The model needs to be revised because:

- The available budget for commercialisation is limited (including pre-launch and go-to-market);
- The window for success is becoming smaller;
- Expectations from different stakeholders in the ecosystem have increased.

Figure 5. The pharma investment life cycle of products in the old days, now and in the future (illustrative)



Therefore, there are three goals that need to be achieved:

- 1 Deep understanding of the customers to define a more focused commercial and medical strategy (e.g. including more targeted training, identification of the most relevant key opinion leaders, ...), as well as building the services for patients, physicians and payers to accelerate adoption. One of the over-performers from Figure 4. excelled in this regard by addressing the key treatment centres in the market early enough, thus securing a significant competitive edge in terms of adoption
- 2 “Activating” the market creating awareness of the disease and adequately communicating why a new or different treatment could have significant benefits; in this vein, another over-performer’s messaging for its new drug that consisted of multiple active ingredients was simple: out of four make one; this addressed exactly what physicians and payers demanded in order to improve patients’ adherence and simplified the lives of the patients significantly
- 3 Strengthening evidence generation in order to demonstrate outcomes which are relevant to the key stakeholders (patients, physicians and payers). The third over-performer achieved excellent product appraisal and appropriate price levels for stakeholders in a fairly crowded indication, even with tough negotiators like in Germany or UK. They achieve this, with highly relevant endpoint and comparator selection in their phase 3 studies by driving an early dialogue with payers and physicians.

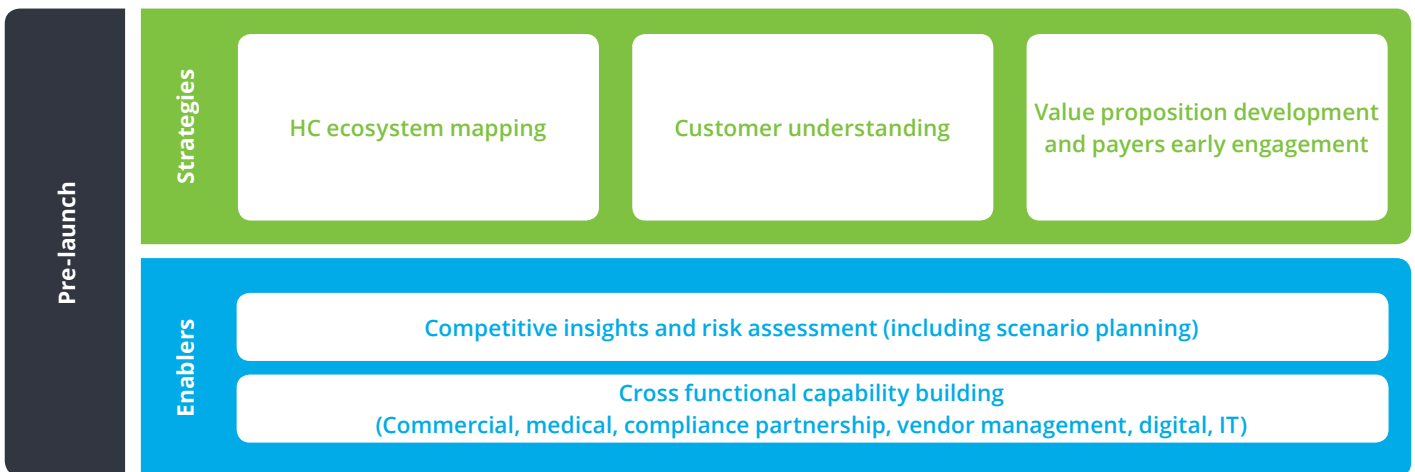
If the above goals are achieved, this would significantly decrease the commercialisation costs and create a steeper uptake curve.

Pre-launch approach

Pre-launch activities need to have a stronger customer focus, including early engagement with customers to co-develop the product value proposition (aligning R&D and Commercial) while capturing insights to inform the commercialisation and access strategy. Furthermore, a critical success factor is to identify the three to four key questions that make each drug launch unique. Identifying these questions early gives pharma companies the opportunity to act and shape the market. Typically, these questions are comprised of:

01. Identifying the dynamics among stakeholders in the ecosystem (healthcare ecosystem mapping)
02. Selecting the key customers and influencers (at any given stage of the life cycle) and identifying interests/needs (customer understanding)
03. Engaging early with payers to shape the value proposition, clinical trials, etc. (payer engagement beyond science)

Figure 6. Key strategies and enablers of a successful pre-launch phase



Source: Deloitte Launch Framework 2018

A successful launch requires three core strategies:

1. Healthcare ecosystem mapping – *Understanding key stakeholders and their role*

Invest to understand the healthcare ecosystem surrounding the targeted disease area in order to map the key stakeholders, customers, influencers and decision makers.

The customer landscape is constantly changing and the need to understand the roles and needs will provide pharma companies with an edge to make the difference:

- **Payers** – Engage early to collaborate on the best market access approach, to gain their buy-in and support from the start
- **Influencers** – Identify and target the most irrelevant influencers
- **Providers** – Understand, simplify and support their interactions with patients, drive shared decision-making
- **Patients** – Understand and simplify patient pathways (shorter, leaner and easier to navigate), and provide patients with the support and services they need.

2. Customer understanding – A targeted approach to identify individual needs

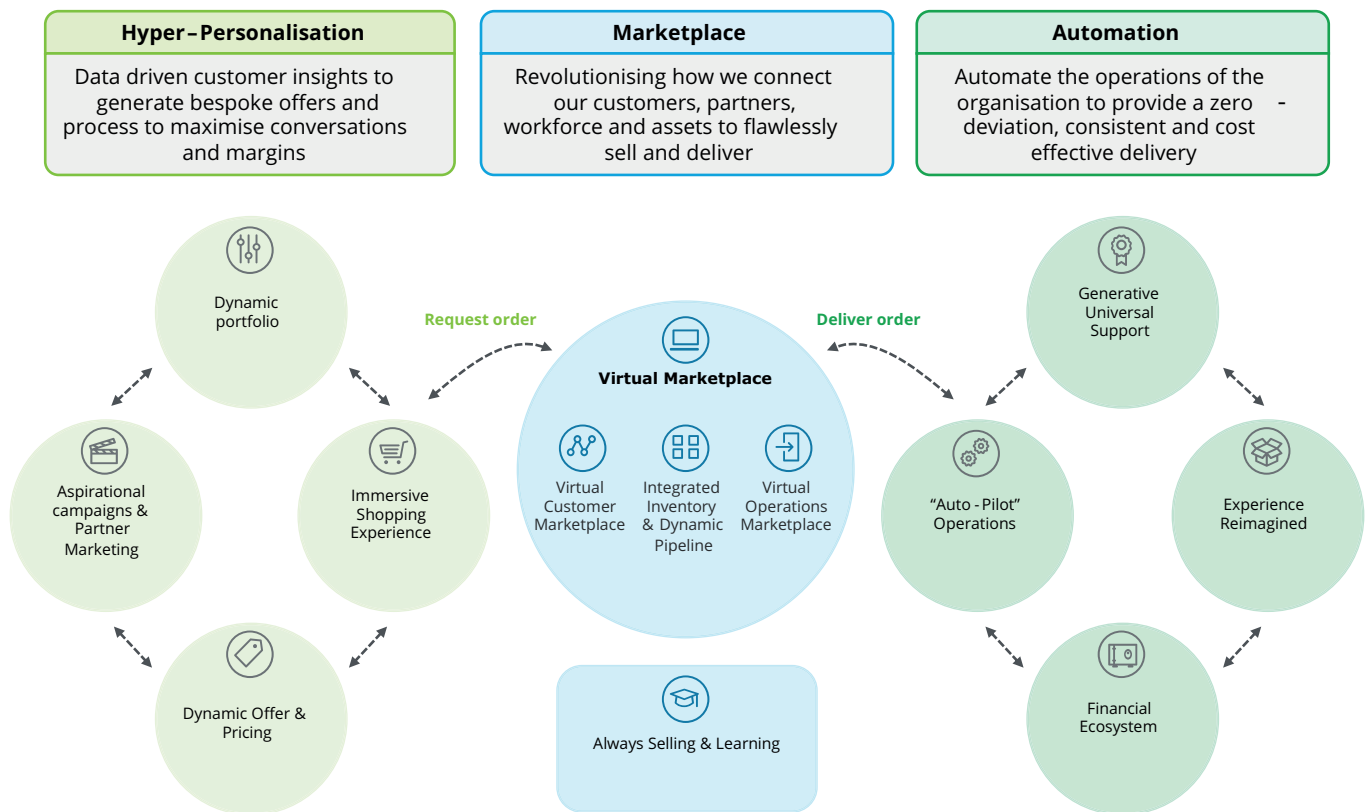
A one size fits all go-to-market model based predominantly on field force deployment does not work anymore. This does not mean replacing traditional channels like sales reps, but rather adopting a more targeted approach leveraging the correct channels based on the needs of each of the stakeholders.

Companies in other industry sectors, from retail to automotive and airlines, have pioneered concepts that biopharmaceutical firms could embrace and adapt. One such example is Tesla's highly integrated, digitalised mastery of the customer's entire journey, from first contact with the brand to after-sales service, with complete pricing transparency and efforts to build trust. Tesla has created an amazing customer experience empowered by a deep understanding of the customer journey.

There are many other pioneering efforts that biopharma can emulate:

- Netflix analyses every customer interaction to predict viewing preferences and deliver personalised recommendations. They also use this data to help determine which new content they should create.
- Emirates' extensive customer journey mapping helped the airline to identify and remedy weak spots and build new relationships, both with its customers and its partners.

Figure 7. Big ideas: Customer understanding



Source: Deloitte framework

3. Payers' early engagement – *Healthcare systems increasingly look for proven outcomes*

Engaging with payers early is increasingly important to ensure pharma companies are able to develop a product's value story that addresses payers' needs. The scientific content is important, but it is not the only thing that matters today.

Payers want to know if the new drug creates value for the healthcare system from an economic stand point (i.e. could a new drug decrease the overall costs associated with the patient's treatment). At the same time, payers are also looking at innovative contracting models to reduce the upfront costs and that are linked to the outcomes of the treatment.

Multi-disciplinary capabilities are required to properly communicate the value message beyond the drug itself. In addition, pharma companies will need to establish partnerships with key stakeholders in the ecosystem to achieve this e.g. the benefits of a drug need to be monitored, preventive treatment requires more accurate diagnosis.

Given the specificities of local healthcare systems, a cross-countries strategy is NOT enough – engagement with local payers can certainly accelerate time to market. Global payer engagement strategies, and communications have to be adapted to local needs.

These core strategies can be enabled by:

4. Competitive insights and risk assessment – *Moving from a backward to forward looking approach*

The level of competition keeps increasing (including generics and biosimilars penetration). Data is available in abundance, but mostly unstructured and from different sources which are not always reliable. Pharma companies have historically looked to the past and reacted. Risks were often only identified the moment they materialised.

A successful launch requires a structured approach to gathering competitive insights. These need to be tied to leading indicators that allow for early risk prediction and action.

Predictive risks and opportunities need to be tracked and summarised in a clear dashboard, which can then prompt strategy, action and / or response.

5. Cross-functional capabilities – *Combining R&D and Commercial forces*

With the growing pressure to decrease the time-to-market, pharma companies should strengthen their cross-functional collaboration. This requires the adoption of a customer-centric approach from development all the way to commercialisation. Commercial teams should be involved early on (from Phase 2b) to ensure the drug will meet customer needs, differentiate from the competition and meet access requirements.

A cross-functional team (R&D and Commercial) needs to be in place, ensuring a strong coordination supported by a clear governance model.

Go-to-market model

In the new context where competition is continuously increasing and customers are more savvy, building an asset light (and asset right) customer-centric and digitally enabled go-to-market model is essential. Being asset light (and asset right) means lowering operating costs and risks (lean approach), focusing on new channels that can deliver a better return and greater flexibility, as well as establishing a multi-disciplinary approach. But it also means leveraging capabilities that are already present in the market (i.e. ecosystem building / partnership model).

We believe the next generation of go-to-market model will be based on three core strategies and two enablers:

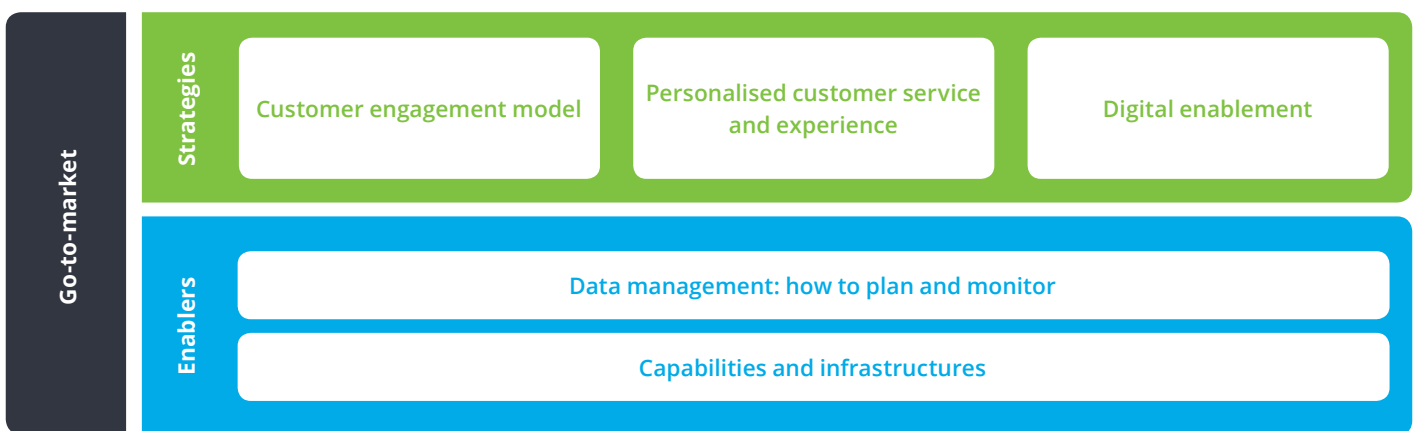


Figure 8: Key activities and enablers of a successful go-to-market model

Source: Deloitte Launch Framework 2018

1. Customer engagement model – *Customer engagement is not a single transaction or one-way communication, it requires more specialised and multi-disciplinary capabilities*

The reality is that pharma companies have to compete mostly with consumer goods companies to gain a share in their customer’s day. The customer day represents all the interactions that a customer has with different brands throughout the day (i.e., brand exposure).

Customer engagement is at the heart of a value-focused commercial model. Engagement isn’t a single transaction or one-way communication. It is, where appropriate, an ongoing dialogue that is as targeted, personal, purposeful and timely as possible. It must also evolve based on feedback and closed loop interaction.

Pharma companies will only be able to create value for their customers and effectively communicate that value if they have a deep understanding of their customer needs. It isn’t straightforward: not all customers want – and thus will be prepared to pay for – the same things. Patients want what is best suited to their condition and lifestyle. Providers want cost-effective, practical tools to improve outcomes. Priorities vary further within these broad customer categories.

In this context, new and specialised field roles are being considered or revamped in lieu of traditional sales reps. Medical Science Liaisons (MSLs), for example, allow pharma companies to engage physicians during clinical trials, long before launch, in a compliant way, and some companies are converting MSLs into field reps after launch in order to exploit the existing relationship between MSLs and physicians.

The field model is evolving from a mono to multi-disciplinary approach. On one hand, physicians are becoming more sophisticated about the type of information they request – that means moving to a more scientific approach (i.e. MSL led). On the other hand, more managerial profiles are being considered in ecosystems where treatment and care decisions are centralised at the public or private institutions level.

Highly connected customers can be engaged across a number of different physical and digital channels. Pharma companies will need to understand their customers need and how they want to be engaged. Pharma needs to use all these channels in order to better understand customers’ needs and to maximise the chance of meeting them. Mastering multi-channel customer engagement is about continuously

adapting and personalising the channel mix according to customers' behaviours and needs, rapidly evolving market dynamics, and product characteristics.

2. Personalised Customer Service and Experience – *Creating valuable solutions now goes beyond demonstrating product efficacy, safety and quality*

In pharma, customer service will be key in delivering a superior customer experience, which should be based on clear customer insights. Creating valuable solutions now goes beyond demonstrating product efficacy, safety and quality. It may include a suite of services along the entire patient journey to support medication adherence, disease management, diagnosis and/or lifestyle. It may include more convenient forms of administration. It may include access to educational materials or a 24-hour nurse telephone hotline.

But adding value to customers is only half the battle; demonstrating and communicating the value of those solutions is just as important as creating them. Pharma companies must be equipped with evidence that supports the value of their solutions to each customer group – patient, payer, provider, and regulator – and to individual customers. They must also speak in a language that the customer understands. Physicians and patients, for example, may think of 'value' as a treatment that can be conveniently administered at home. Payers may see 'value' as a competitive up-front price or an outcomes-focused reimbursement deal. Pharma companies need to understand what will engage each stakeholder group and communicate it with appropriate messaging and through the appropriate channel.

3. Digital enablement – *Imagine a Pharma company where 70 percent of commercial costs are for digital channels*

Looking to the future, pharma's adoption of patient engagement strategies is inextricably linked to its digital technology enabled transition to 'wraparound' solutions and a focus on improved outcomes. New disruptive technologies, like blockchain, gamification and 3D printing will provide further opportunities to guarantee the sustainability and growth of a more patient-centric pharma industry.⁹

Patients are becoming increasingly connected via mobile technology and social media. The increased connectivity will have a profound impact on how pharma and other stakeholders in the health ecosystem engage with patients¹⁰. For instance, patients are much better informed prior to visiting their physician, thanks to a growing number of online educational resources including platforms such as PatientsLikeMe where people exchange stories. The same goes for healthcare professionals as well: 85 percent of physicians in the USA feel that digital health solutions are helpful in caring for patients, according to a 2016 American Medical Association survey¹¹. Payers are also benefitting, by leveraging the data generated by patients' growing digital footprint. Formulary decisions are therefore increasingly being based on real world evidence demonstrating a treatment's efficacy.

In 2017, it was estimated that there were 325,000 mHealth apps on the market, 78,000 added during the last year which collectively generated 3.6 billion downloads¹².

Since pharma companies are not exclusively controlling the flow of information to the healthcare ecosystem, as part of their move to more patient-centric strategies, they need to be mindful of these trends and capitalise on patients' familiarity and use of smartphone apps to engage more effectively with them.

4. Data management: how to plan and monitor – *Go beyond traditional data*

In an ever evolving environment, the data gathered, how it is handled and governed and what insight is generated becomes extremely important. Pharma companies need to have a data strategy as an essential part of product launch activities that allows them to be proactive in the market, anticipate key challenges and capture opportunities.

Data is at the heart of a successful customer centric approach: from an early understanding of the customer needs (before the product has been launched, in a compliant way) to a continuously improved go-to-market strategy.

Traditional data sources (e.g. prescription data) are not enough to understand the customer needs – these are backward looking, and would only partially inform a differentiating launch strategy.

There are innovative data sources and techniques (e.g. social media monitoring, voice of the customer) that can provide a better

understanding of the needs of customers (including patients, physicians,...). If this information is properly captured, it would allow pharma companies to create differentiating customer experiences and services.

But this still remains a static picture. Advanced analytics is essential to ensure continuous improvement in how pharma companies engage with customers.

5. Capabilities and Infrastructures – *Embed IT capabilities in the commercial teams*

All these changes in the pharma environment (e.g. new customer engagement model, personalised customer experience and services, and digital disruption) require a completely new set of capabilities and infrastructure. The key to success is to embed these in the launch plan, in order to maximise each element of the go-to-market model once the product is on the market.

The new model demands a more agile mind-set amongst all customer-facing and commercial teams, as well as in the supporting functions. Content creation and sign-off processes must be fast, dynamic and flexible, which is currently not the case within most biopharma firms. Customer insight must be integrated and feed into brand planning in a dynamic and timely fashion.

The model also requires a robust, integrated IT infrastructure – including data analytics processes and systems that can identify customers' behaviours and channel preferences. But most importantly, it is critical for IT teams to be embedded within the commercial teams and engaged in helping the commercial teams achieve their customer-engagement goals, rather than simply supplying the technology.



C-suite take away

How to start the engine under the new paradigm?

Pharma companies should consider investing more resources during the pre-launch phase with a customer centric approach.

In line with this recommendation, the following key actions should be taken into close consideration:

- **Prioritise pipeline assets.** Adopt a portfolio approach rather than a product approach, which requires investment and resource allocation on fewer selected assets that are expected to be blockbusters.
- **Free up resources to finance the pre-launch activities of the next blockbuster drug.** Prioritise the key in-line products for investment and adopt a more agile, customer centric and digitally enabled go-to-market model. Anticipating the investments and investing more in pre-launch insights and activities prevents reactive actions post-launch that are typically very costly and have a limited impact.
- **Invest in understanding the product ecosystem.** Map the key stakeholders (patients, physicians, payers and healthcare providers) to identify what their prioritised needs are and how to address them in a differentiating way. In the current context this would require earlier and deeper analysis and research to identify the three to four swing factors to shape the market.
- **Create a company launch excellence mind-set.** Create a common way of thinking to improve the quality and decision-making speed, and its execution. Establish integrated and cross-functional collaboration, with early engagement between R&D and Commercial.
- **Build the capabilities early.** Consider the relevant capabilities to execute launch excellence, including where and how to apply data insights, and how to align with the cultural change agenda.
- **Challenge the current go-to-market model.** Adopt a “zero-based budget” mind set and configure your organisation, and the capabilities within it, to follow a disciplined and consistent process that will reliably find for each launch the three to five levers directly linked to your profitability.
- **Invest more in commercial functions teams.** Train multi-disciplinary skills, establish clear career development paths and institutionalise a code to be successful within the organisation. Set clear accountability and empower talents.

Endnotes

01. Phases 2b and 3 refer to clinical trial phases, phase 2 trials establish proof-of-concept and phase 3 trials establish the efficacy and safety of the treatment in humans
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