Launch Excellence in a disrupted world: **challenges and opportunity**

Since 2007 IQVIA has examined which launches have been the most commercially successful in the recent timeframe, of innovative, protected new products. The findings have been published in a series of Launch Excellence studies. In this article **Sarah Rickwood, Markus Gores, Yasemin Karanis,** and **Alexandra Smith** present some of the key findings, the fundamentals for achieving a successful launch and long-term trends driving the launch environment.

A consistently compelling finding of the entire Launch Excellence series is the six-month window of opportunity which shows the significance of early performance. Speciality launches dominate in excellence, and is winning in the long term, even amongst older products. It is tough to achieve consistent launch excellence across countries, only few launches meet the base criteria for an excellent launch internationally.

The global pharmaceutical industry is changing, as is the environment for innovative product launch [Figure 1]. Molecular innovation is being supplemented, and in some instances could be replaced, by other forms of innovation, including highly individualised, procedure-like cell and gene therapies.

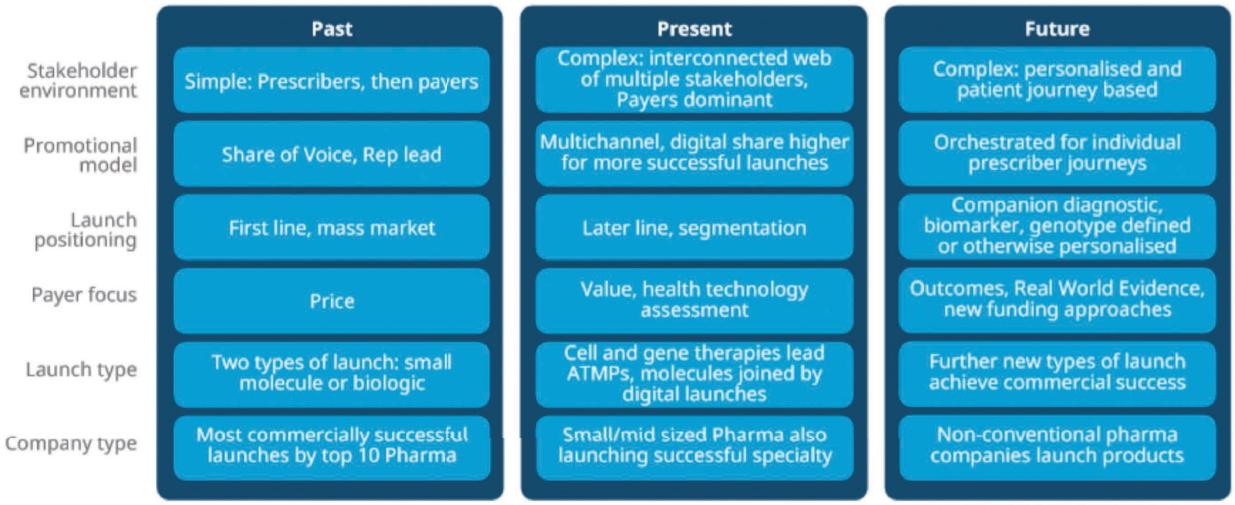
The nature of launches will continue to evolve, faster than ever before. However, the fundamentals of Launch Excellence remain the same.

The rise of specialty as the key value growth driver of the developed markets, has created a situation where most launches, and almost 100 percent of the most successful launches, are for globally small, sometimes tiny, patient populations. 2018 was the first year in which both the FDA and the EMA approved more Orphan medicines, for rare diseases, than mainstream products.

Mass market common, chronic diseases of the elderly don't drive pharmaceutical value growth anymore; increasingly, value growth is a product of high value therapies for small patient populations.

For multi-indicational products, launch is no longer a one-off event. In addition, faster approvals on early clinical data and longer journeys to full market access, due to extended real world assessment, create an extended launch period. Also, full life-time value must be considered. A product may have 10 indications during its full lifecycle.

Figure 1: How has the launch environment changed?



The class of 2019 specialty dominates in both achievement and in return on investment

In our Launch Excellence reports we have sought balance between consistency of analysis and adaptation to the changing realities of the launch environment – the biggest change being the vertiginous rise in the number and commercial impact of specialty launches, especially oncologicals.

In Launch Excellence Report V, specialty products outperformed primary care launches on all Launch Excellence measures, and only specialty products were in the elite group of launches which performed consistently excellently across countries. Primary care launches operate in a more constrained environment, and at present the overall opportunity for these products is often reduced.

Of 136 specialty launches analysed across seven countries (US, top 5 Europe, Japan) 8 percent (11 products) met our base three criteria in more than one country. Of the 146 primary care launches, 5 percent (7 products) did the same. Overall, 6 percent of the cohort of specialty and primary care launches met our three base criteria internationally. To achieve consistent Launch Excellence across countries is extremely tough.

We also analysed launch investment, the promotional activities, non-digital and digital, addressed to healthcare professionals, as measured by IQVIA's ChannelDynamicsTM audit. True Launch Excellence should not be bought at any price. Our findings show that a greater proportion of specialty brands are both excellent and have high return on investment. However, a top best seller is not always example of an Excellent launch due to promotional out-performance – e.g. exceptionally high investments during the first two years.

The significance of early performance

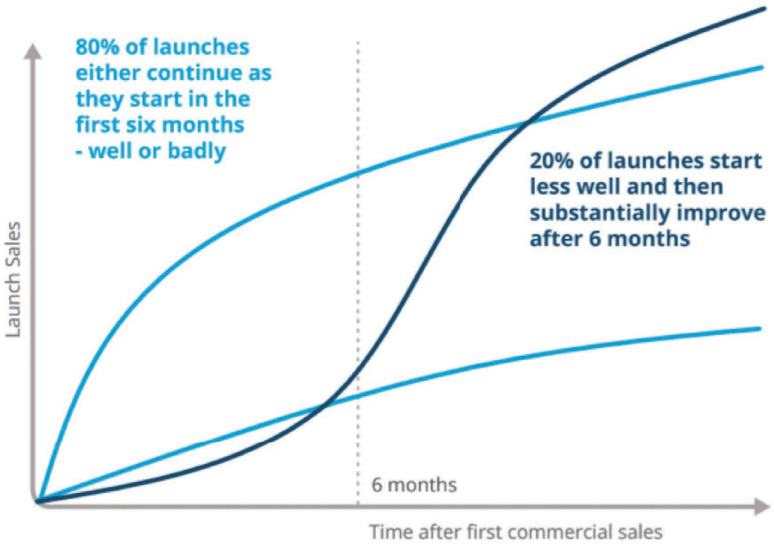
One of the most consistently compelling findings of the entire Launch Excellence series is the six-month window of opportunity [Figure 2]. It measures the degree to which launches change their country level sales trajectories between six months and two years. A steep, sustained uptake curve is the goal for all launches, but is not always achieved. On average, 20 percent of the launches significantly improve on their first six months, 80 percent, on average, do not – they either remain in the same decile, move up or down only to the one adjacent. The six-month window does NOT say that no launch can improve its trajectory after six months on the market – in fact, an average of 20 percent of them do improve.

The longer-term prognosis for launches that fail to improve in their first six months is more challenging. There are exceptions, but for most the rule is that early performance, good or bad, is strongly influential.

IQVIA's six-month window insight has been closely scrutinized over the 12 years and maintained.

Multiple factors influence postlaunch sales trajectories – new indications can add incremental patient opportunities, market access decisions can boost or kill sales trajec-

Figure 2: Launch Excellence six-month window explained: it's an 80/20 rule.



- The majority of launches have their longer term fate determined in the first six months of their commercial life
- It is possible to improve after the six month window – 20% of launches do
- The 80/20 rule has been consistent since the first 2007 Launch Excellence study, over time and countries despite the rise of Health Technology Assessments and payer power
- In Launch Excellence VI we have analysed using absolute rather than relative rankings, but the 80/20 rule mostly remains

Source: IQVIA European Thought Leadership

tories. The six-month window shows that these factors improve the shape of the uptake curve for a minority of launches – albeit a reasonably sizeable one.

Key lessons:

There is no substitute for effective pre-launch preparation

Every launch should be prepared as if it were destined to be in the 80 percent, not the 20. "In-flight" correction cannot substitute for early, systematic, high quality launch preparation, country by country, function by function.

See the wood for the trees

Seeing the wood for the trees refers to the smarter use of Launch Preparation planning. Be comprehensive but discriminate between the tasks that are mission critical for that specific launch's Critical Success Factors, and need priority and resource, country by country, and the other necessary, but non-critical tasks. Comprehensive Launch Preparation plans risk becoming the purpose rather than the means to achieve the purpose.

Speciality launch exellence

Highly multi-indicational products drive growth

Traditional single indication launches, such as Lipitor, were a sprint with focus on the early years. However, as companies recognised the potential of the "fulfilling life" a product can achieve, investment became long and sustained throughout the product lifecycle.

New launches that are multi-indicational has not increased systematically, growth is driven by the launch of highly multi-indicational products. One key example is the advent of Immuno-Oncology (IO) products which took multi-indication to a whole new level by targeting a key hallmark of cancer that is present across multiple tumour types – the ability to avoid immune destruction.

Not just a sprint but, a marathon too

Brands which launch into multiple indications will require evolutions of Launch behaviours, budgets, and performance management. Multi-indicational launches expose the stresses of launch preparation and execution complexity:

- Stretched and competing budget priorities
- Maintaining continuity and focus
- Maintaining energy and communication across countries

Segmentation is now almost always the future for Launch Excellence, because regulators and payers are seeking certainty of superior outcomes and on budget impact, which is much more difficult to deliver initially in broader populations and with less mature data.

The classic dilemma of launch, the choice between to go narrow or broad, known as "segmentation anxiety", is no longer an option in primary care, mass market disease areas with the existence of perfectly effective generics.

What are the fundamentals of achiving an exellent launch?

We always describe the foundational success factors of Launch Excellence as "Easy to say, difficult to achieve". They are consistently relevant across launch types, countries, and throughout our Launch Excellence studies:

A powerful and pertinent value proposition

When a launch enters commercialisation, generally early in Phase III, many of the clinical decisions for the final product will have been made, but not all. Multi-indicational products may still have clinical development strategy to be executed post initial launch. For all products, continued development of Real-World Evidence during and post launch is now an essential element of building a powerful and pertinent value proposition.

IQVIA's Launch Archetyping Methodology categorises launches using a detailed, objective approach, by how differentiated they are, and the level of unmet need of the therapeutic area into which they will launch. Unsurprisingly, there's a greater proportion of commercially successful launches falling into the highly differentiated, high unmet need market quadrant than elsewhere. Differences in commercial success between products lies in the stakeholder engagement and the alignment behind the execution of the launch.

Effective and efficient stakeholder engagement

Companies start preparing Excellent launches with a carefully researched stakeholder map. They create an investment and activity plan against each stakeholder to have the optimal awareness and perception of the launch product, and readiness to act on that perception, at the time of launch.

An aligned and prepared organisation

The most important foundational success factor of all is an aligned and prepared organisation. It is also the most difficult to achieve, for a single launch, let alone for multiple launches, which is what companies increasingly must accomplish.

An inverse relationship

An interesting finding is that the more launches a company made in the time-period covered by the Launch Excellence cohort, the lower the percentage of those launches that were Excellent by our classification. Or, the more you launch the less excellent you get. There were two responses to this finding: the first argued the finding must be incorrect – companies launching more products should be learning from their experience, and the proportion of a company's launches that are Excellent should, consequently, improve. The counterargument is that the finding is true because multiple launches compete for budgets, management attention, priority and focus. Companies fail to manage that competition effectively – after all, a single launch is a hugely complex, multifunctional, multinational endeavour; five or six is a tremendous challenge.

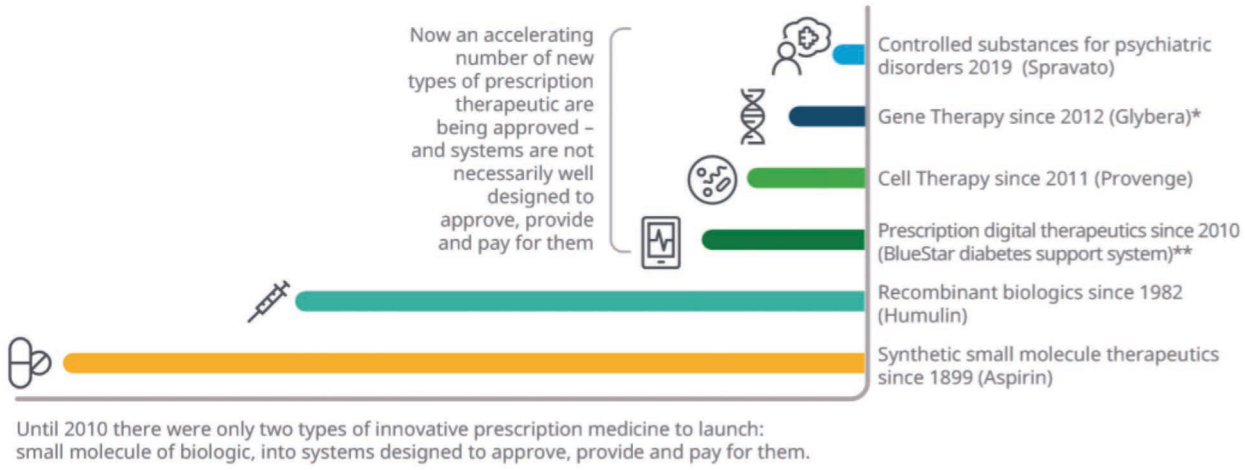
In practice, IQVIA's experience with companies addressing multiple launch is that both drivers happen – a multiple launch situation will never cease to be an extraordinarily complex challenge, but the best companies recognise this and have structures and processes in place to address it.

In future this will matter more, because most companies will be faced with more, but smaller launches, driven by two trends:

- Opportunity fragmentation; innovation focusing on smaller sub-populations while high prices are coming under pressure, but companies must still deliver absolute growth targets.

- Multi-indications; if different indications target different healthcare professional universes.

Figure 3: Prescription launch offering types have multiplied since 2010 – as will launch challenges.



Notes: *Gendicine was approved in China in 2003, but Glybera was first gene therapy approved by EMA and FDA
**First standalone prescription digital therapeutic (reSET) approved by FDA November 2018

The future of launch

New types of therapeutic launches create challenges

For more than a century the prescription medicines industry has been driven by innovation, and until very recently, focused almost exclusively on the molecule in two basic types – small or biologic. This is changing, rapidly, as Figure 3 shows.

In 2016, Spinraza (nusinersen) for Spinal Muscular Atrophy, became the first truly commercially successful gene therapy launch.

For autologous cell therapy launch success manufacturing strategy is a key element. Location of facilities is critical due to restrictions on the testing and export of human cells. Manufacturing is labour intensive and, initially, unautomated. Cost of goods is significant, cost reduction a challenge. The companies which most successfully address this challenge will also be most successful in long term launch.

As patient numbers ramp up, other challenges of consistent quality, demand management and capacity will come to the fore.

Prescription Digital Therapeutics (PDTs) is a broad and evolving group of offerings. In 2018 FDA approved reSet, the first prescription software claiming specific therapeutic benefits, supported by clinical data, for pa-

IQVIA:s global database, MIDAS, provide unmatched quantitative evidence base in research on launch. By using largely consistent data and analytics since 2007 IQVIA build a unique, quantified view of the way in which commercial success has changed over years. Examining launches on a country by country basis provides an understanding of the most common reasons why launches do not reach their full potential.

tients with substance use disorders. It is a 12-week series of interactive treatment modules delivering cognitive behavioural therapy, to be used in conjunction with outpatient care. PDTs have the potential for genuine equivalence to molecular therapeutics, but substantial barriers remain before they can be routinely prescribed and reimbursed.

Prescription, reimbursement and appropriate price points exemplify some of the launch challenges of creating new types of therapeutic launch. The market is not a global one – different countries are at quite different stages of development.

Conclusion

The nature of launches will continue to evolve, faster than ever before, but the fundamentals of Launch Excellence at heart remain the same.

At the heart of all Excellent launch preparation, whether for a single or for multiple launch, is a focused, actionable, aligned, realistic group of critical success factors tailored for that launch, which have been identified as the critical factors necessary to exist in the launch period for optimal success. These must be defined and limited in number, actionable and aligned across the organisation, and aspirational but realistic.

Easy to say, difficult to achieve.

This is a shortened version of the full white paper which is available for downloading at IQVIA.com

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