

Launch Excellence V

Surviving and thriving when launching in an increasingly specialised world

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Introduction

The next decade will see greater concentration of competition for innovative Launches, with focus turning to more specialist therapy areas, limited key launch countries, healthcare budgets, doctor attention time, and even patients. Achieving true Launch Excellence will become even more challenging. To understand how to succeed in the future, companies must first understand how today's launch environment drivers came to be.

Ten years ago, IMS Health (now QuintilesIMS) published a white paper entitled "Launch Excellence". It defined objective criteria for excellence in launch for prescription medicines, and developed in-depth insight on medicines that achieved them. We drew tough but surprising conclusions. For example, that the first six months has a disproportionate influence on later success for at least 80% of launches in any country. New Chemical Entity launch success is still, overwhelmingly, a developed markets game: 86% of the first five years' sales of New Chemical Entities launches since 2005 came from just seven countries: the US, Japan, Germany, France, UK, Spain and Italy.

Our interviews with companies preparing for launch suggest the overwhelming majority, if asked, will classify themselves as "behind" on some or all aspects of their launch preparation. But some of these companies will go on to have excellent launches- others will not. Quality of preparation matters as well as quantity.

86%

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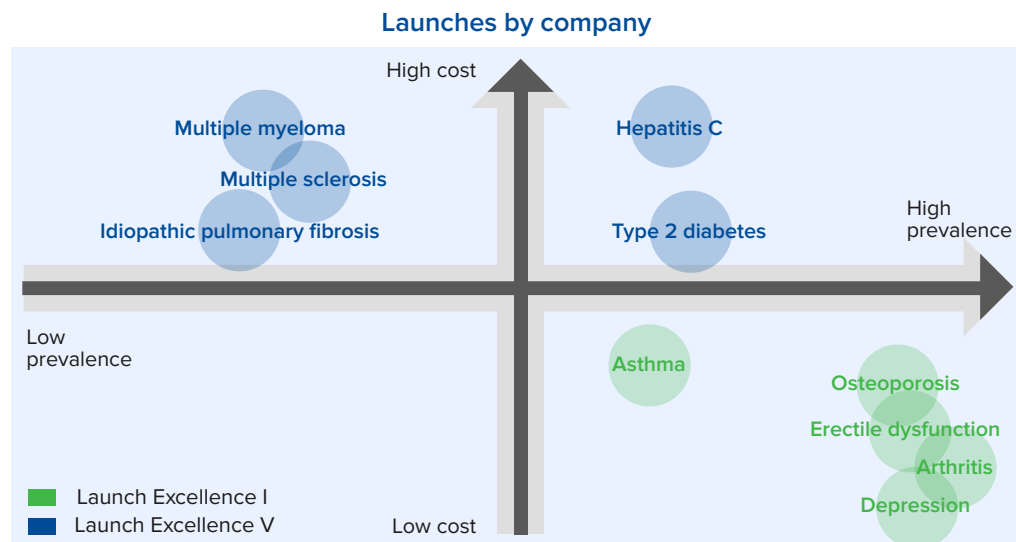
A decade of Launch Excellence insight: what does it tell us about the future of the pharmaceutical industry?

Launch Excellence is at the heart of many of the fundamental changes in the pharmaceutical industry's landscape. Launches drive pharmaceutical industry change, so excellence in launch is the key to the pharmaceutical industry's future.

The decisive shift to specialty pharmaceutical product value growth

The first Launch Excellence white paper analysed launches back to 1995, an almost Jurassic era when the big beasts of the pharmaceutical launch world were primary care, mass market products: Lipitor, Plavix, Seretide, or Detrusitol. All of these products were blockbusters in the billion dollars/year sense of the term but were very different to today's tranche of launches, whether excellent or not, as Figure 1 outlines.

Figure 1: LE 1 drugs were without exception lower cost products for higher prevalence conditions

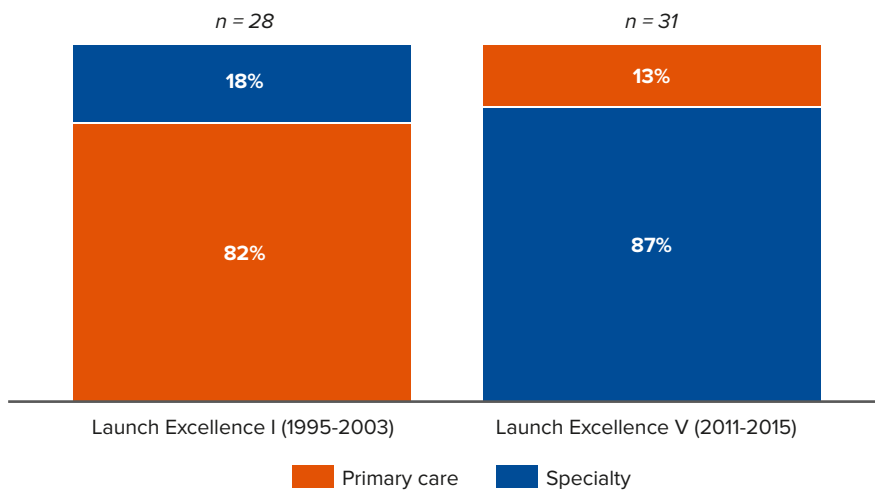


Source: QuintilesIMS Thought Leadership Launch Excellence I and V; QuintilesIMS Pricing Insights; QuintilesIMS New Product Focus
LE1 drugs were launched between 1995-2001 and LEV drugs were launched 2011-2015

As Figure 2 shows, today's Excellent launches are largely high cost products aimed at low prevalence diseases treated by specialists. This reflects, largely, the Universe from which the Excellent launches are sifted. This shift in scale has paved the way, at least in part, for specialty companies with smaller-scale global commercial infrastructure to achieve outstanding launch success.

Figure 2: We are truly in the era of Specialty – very few primary care launches excel globally

Proportion of Globally Excellent Launches by Primary care/specialty in LE I vs LE V



Notes: LEI drugs were launched between 1995-2001 and LEV drugs were launched 2011-2015
 Source: QuintilesIMS Thought Leadership Launch Excellence I and V

In the late 1990s, the launch of the first biologic disease-modifying agents for rheumatoid arthritis, and targeted treatments for oncology sowed the seeds of the specialty revolution. Specialty products, biologics or otherwise (all biologics apart from insulins are specialty products), share common characteristics:



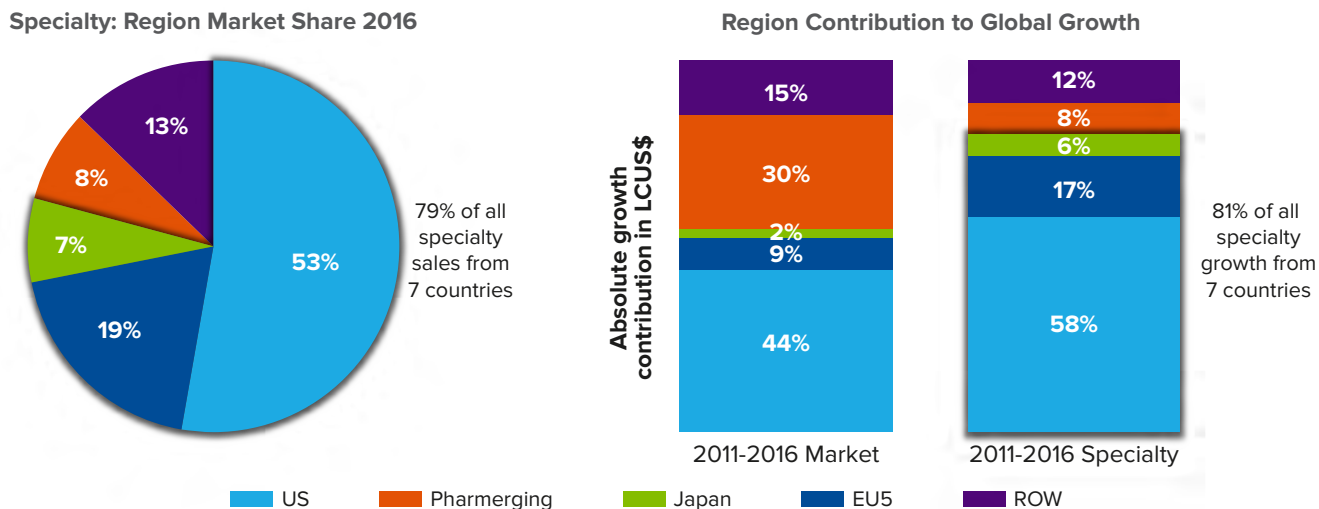
While specialty is now 30% of global prescription medicines sales value, it approaches half of all medicines spending in the key developed markets.

- Treat complex and serious diseases
- Prescribed by specialists
- Usually expensive, with specialised distribution routes or methods of administration

Specialty products are now leading drivers of value growth for the global pharmaceutical market. While specialty is now 30% of global prescription medicines sales value, it approaches half of all medicines spending in the key developed markets of the US, Japan and EU 5. For these key regions, specialty provides the vast majority of current and future value growth.

This shift to specialty value brings a host of profound changes. It has narrowed the focus of launch success to a small number of developed, wealthy countries, for example. As Figure 3 shows, total of 79% of all specialty value and 81% of growth in the global pharmaceutical market comes from just seven countries: the US, Japan, Germany, France, Italy, Spain and the UK. These are also the markets which account for 86% of all first five year innovative launch sales.

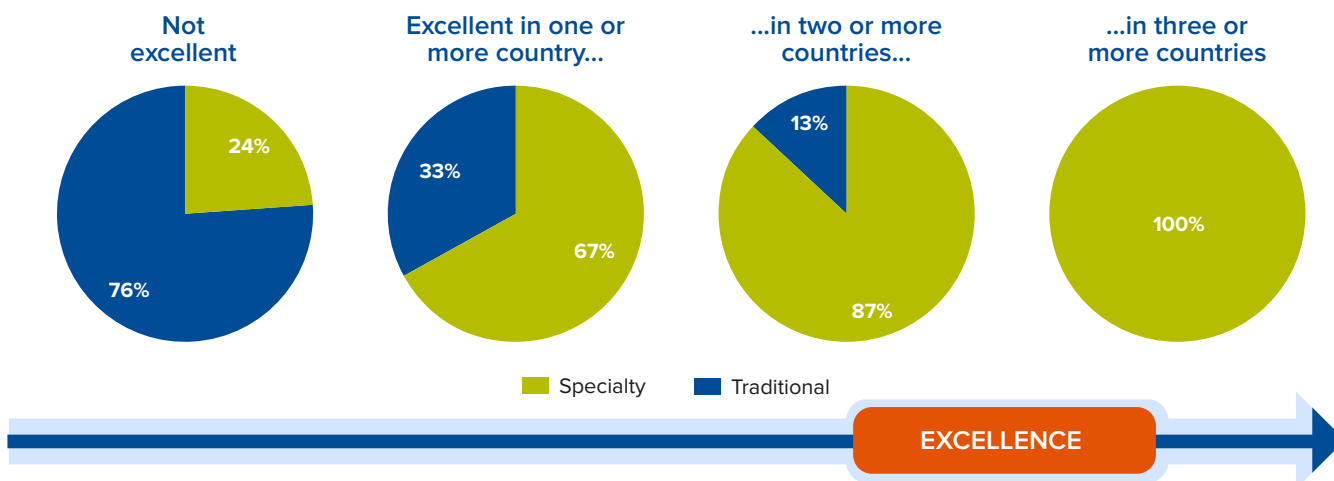
Figure 3: 7 developed countries, including EU5, are 79% of all specialty sales and 81% of all specialty growth



Source: QuintilesIMS MIDAS Q4 2016

In Launch Excellence V, as Figure 4 shows, many more specialty than primary care launches are globally excellent; primary care – with the notable exception of diabetes – now has a patchier launch track record. Primary care sales value has grown in the US and Japan but stalled in Europe, and partly by the international nature of the specialty environment from an influencer/prescriber perspective.

Figure 4: Breakdown of specialty and traditional launches by global excellence achievement



Source: QuintilesIMS Thought Leadership Launch Excellence model

Huge NCE launch focus on developed markets

The key emerging markets, which QuintilesIMS terms pharmerging markets, have never been strong contributors to the early sales of New Chemical Entity launches. Of 120 NCE launches which entered the world market between 2005 and 2015, only 2.1% of aggregate sales five years post launch came from the BRICTM markets- that is, Brazil, Russia, India, China, Turkey and Mexico.

The low contribution of the BRICTM to NCE global success is not new. It is a fundamental difference between pharmerging and developed markets and is unlikely to change in the near future. In fact, weakening of emerging economies and their lack of widely accessible high-quality healthcare to support sophisticated, expensive specialty launches, will only exacerbate this disparity.

Decreasing target patient populations

More than 80% of the Excellent launches of Launch Excellence I were primary care products. They were oral contraceptives, or treated dyslipidaemia, hypertension, depression, asthma, osteoporosis, COPD, osteoarthritis and overactive bladder - conditions with global prevalence in the hundreds of millions, or billions. As Excellent launches like Lipitor, Plavix, or Diovan became blockbusters and then genericised, they made low cost, effective treatments available for the first time. This satisfied unmet need and substantially reduced the market opportunity for similar later entrants. There was immediate impact: Novartis's Diovan follow up, Rasilez/Tekturna, failed to match Diovan's success and now sells less than \$200m worldwide, even though patents do not start to expire until 2020.

The drastic reduction in high unmet need in primary care is one of the reasons why most of the subsequent Excellent launches are in specialty areas, where treatment was often unsatisfactory, old, or non-existent, and unmet need was high. The most recent tranche of Excellent launches have very different target populations from those of LEI. Even relatively common and high profile cancers, such as Lung or Prostate, have an estimated annual incidence and prevalence in the low millions globally¹ – and the specific cancer stages and/or subtypes that new launches target are smaller still. The very few Excellent launches in LEV for high prevalence diseases, in the order of hundreds of millions, are in Hepatitis C and Type II diabetes (these are also the drugs with the best uptake trajectories in Pharmerging markets). In fact, diabetes is the only therapy area to feature Excellent launches in both the first and the latest Launch Excellence studies.

What happened to the primary care market is now happening in specialty. The maturation of many specialty therapy areas, for example, autoimmune biologics, has started, and will accelerate over the next decade. This means the variety of situations which new specialty Launches will encounter will increase, with many more having less differentiation and launching into areas with lower unmet need. Some companies will launch into entirely specialty new therapy areas with no existing treatments, and those new areas will increasingly be for rare or ultra-rare diseases. However, for many companies their challenge will be to make a success of a specialty launch into an existing and maturing therapy area with decreasing unmet need.

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A growing minority of new launches are now for rare or ultra-rare diseases. Taken as a whole, the unmet need in rare diseases (defined in the US as fewer than 200,000 patients per condition) is substantial. An estimated 300 million individuals globally suffer from such a disease, half of those affected are children, diagnosis times are lengthy, and only 5% of such conditions are currently treatable. Yet each condition has at most a few million sufferers, and the very rarest may have only tens of patients. Rare diseases are often genetic in origin, with distributions within a few countries – 10% of the global cystic fibrosis (CF) population, for example, lives in the UK. Locating rare disease patients is becoming easier, as sequencing costs drop and patient networks improve, but for rare disease launches, there is no wide-scale global opportunity.



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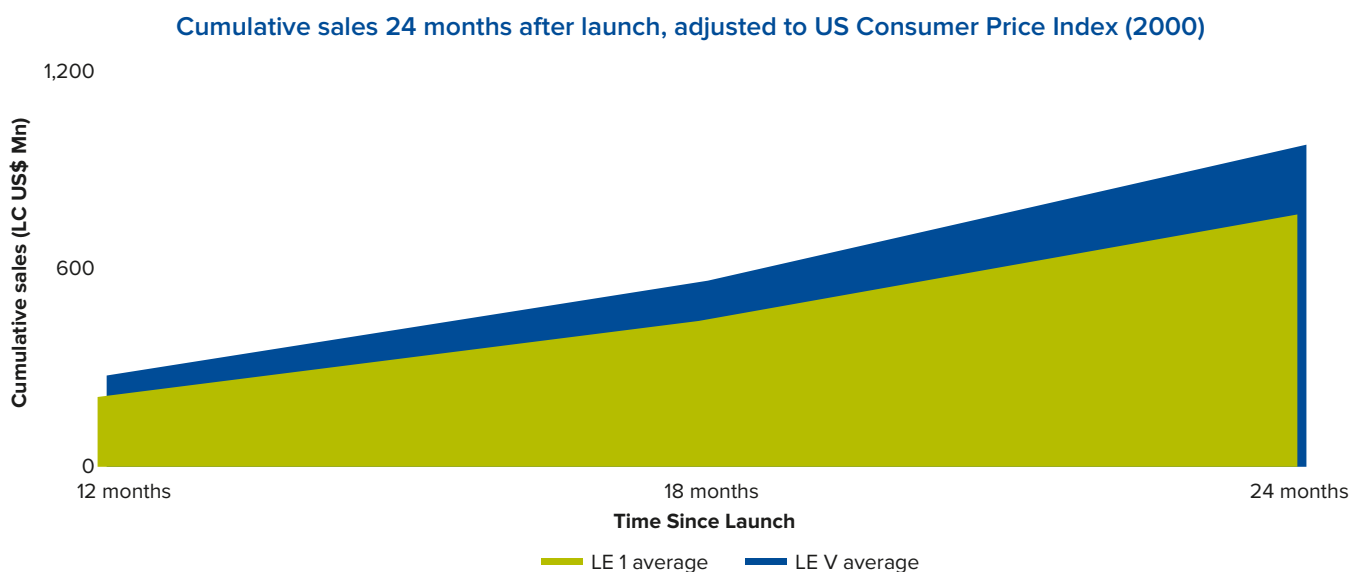
Higher launch product cost per patient

Launch Excellence I primary care products had list prices in the order of a few hundreds to a few thousands of dollars a year in the US and other developed markets. A statin such as Lipitor, for example, was priced at a dollar a day (generic atorvastatin is cheaper still). This made sense for what were often preventative / symptomatic treatments for high prevalence and chronic conditions.

Costs for Launch Excellence V outstanding launches, meanwhile, typically range from \$10k-\$100k plus per year. For many of these treatments the value proposition is quite different to that of earlier excellent launches. Sovaldi and Harvoni, for example, offer rapid and highly effective cures for a disease, Hepatitis C, with serious and life threatening potential consequences. In the case of excellent oncological launches, there have been some significant improvements in outcomes for previously intractable cancers.

This price differential correlates only with limited increased returns for companies, when adjusted for inflation. As Figure 5 shows, the average sales post-launch for Excellent drugs launched in 1995-2003 are not substantially lower than those launched 2011-2015.

Figure 5: Returns for top drugs in LEV are higher – but not dramatically – excluding the Hepatitis C drugs.



Sources: European Thought Leadership Launch Excellence I and V model; Consumer Price Index, US Bureau of Labor Statistics

The implication of these macro launch trends

Taken as a whole, the implications of these trends for launches is a greater focus in terms of opportunity but also risk:

- The US, Japan, Germany, France, Italy, Spain and the UK, account for 86% of all NCE launch sales, and for specialty launches the share is higher still. Pharmerging markets have had historically low levels of contribution to NCE global sales, and a combination of pharmerging market slowdown and the specialist and expensive nature of many new launches will aggravate this. **A narrower country focus can have advantages, but also concentrates risk. If a product launches poorly in the US, or worse, the US becomes a less attractive launch market, launches suffer globally, and there are no country alternatives to make up the deficit. Increased pressure on pricing and a volatile political situation in the US raises the risk for future launches; companies need to insulate against this by optimizing ex-US sales.**
- The annual patient populations that launches (Excellent or otherwise) target, have dropped from a typical 100s of millions of patients globally to a few million. Genotyping and other population segmentation methodologies are likely to perpetuate this trend. Small patient populations are cared for by small numbers of specialist healthcare professionals. The value of individuals grows exponentially, and pharmaceutical companies must not only understand them better but, in an ethical and patient-lead fashion, develop effective relationships with them. **Patient-centricity is not just a gimmick or a slogan, but an absolute necessity.** Likewise, the value of each pharmaceutical company interaction with the healthcare professionals treating and supporting these patients has also risen sharply – at a time when getting face to face interaction with doctors has become even more challenging. **A mature multichannel model which allows consistent and effective communication across a broad spectrum of channels is absolutely essential.**
- As patient numbers have declined, the annual cost per patient for many new launches has risen. In many cases this accompanies a breakthrough in the treatment of a serious disease. **Stress points in the dialogue with payers are growing, however, and launches, excellent and non-excellent, drive this. Drug pricing is an easy target for policymakers to cut healthcare spending. New approaches to break the deadlock between payers and companies on price and market access are an essential part of Launch Excellence**

These factors raise two broader questions:

In an era when pressure on costs has never been fiercer, and issues such as the growing funding crisis in social care intensify scrutiny of healthcare spend, are the trends in innovation and launch sustainable? The age of easy wins in both primary care and specialty has come to an end. Companies may need to revise their expectations of launch from high, fast success to steady incremental increases within boundaries negotiated with payers.

Are today's launches truly addressing the largest unmet needs in terms of both severity of disease and number of affected patients? Large unmet need undoubtedly exist in areas such as CNS and pain, which have seen several cycles of innovation, now largely or entirely genericised. Can companies address these with new types of Excellent launch that demonstrate credible value for the sub-populations with remaining unmet need?

Launch Archetypes

The first wave of primary care excellent launches have genericised and pioneer specialty launches have matured. This means that there are multiple situations a new launch could now enter. Using its database of hundreds of launches, QuintilesIMS has defined four Launch Archetypes – situations encountered repeatedly across therapy areas and countries. The common, defining characteristics are based on the level of differentiation of the product and the unmet need within its disease area:

1. **“Science sells”** – high unmet need and high product differentiation
2. **“It’s about shaping the market/product”** – low unmet need and high product differentiation
3. **“Emphasise the difference”**- high unmet need and low product differentiation
4. **“Who benefits”** – low unmet need and low product differentiation

Regardless of whether products are launching into mass market, primary care or highly specialist, narrow patient population therapy areas, we found multiple launches which fitted into each category, with profoundly different outcomes dependent upon archetype – the logical reaction by the market to each Launch situation. “Science sells” launches averaged the highest sales in their first year whereas the “Who benefits” launches of low differentiation into a low unmet need market averaged significantly less in their first year. Archetypes 2 (“Shaping the market/product”) and 3 (“Emphasise the difference”) fall between these two extremes but it is differentiation that is the more decisive driver.

The market rewards unmet need and product differentiation, but where unmet need is low, a well differentiated product needs a certain extra promotional “push” to thrive.

We applied these Launch Archetypes across the US and Europe with very similar results. And the launches which are found to be “good” by the Archetype criteria also feature in the Launch Excellence Excellent Launches list. As we discuss the Launch Excellence V findings we will be identifying the places where the insights from Launch Archetypes explain the drivers of excellence for key launches.



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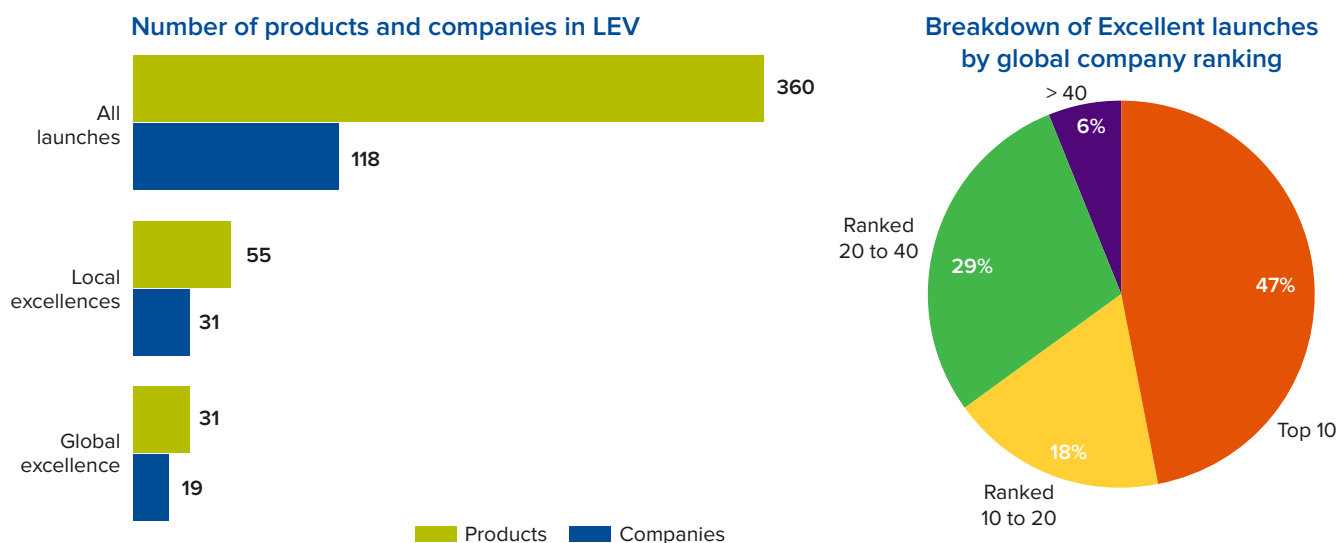
The Launch Excellence V study: approach

Our Launch Excellence V methodology retained the analytic techniques of earlier studies, enabling direct comparisons across different eras. We used QuintilesIMS MIDAS sales audit to quantify commercial success. We used ChannelDynamics™ for insight into post launch promotional investment. This differs from the promotional audit used in previous LE studies. ChannelDynamics™ has a broader coverage of healthcare professionals, especially specialists, and a wider coverage of promotional channels, including, crucially, five digital channels. The analytic approach to identifying Excellent Launches is outlined in the Appendix to this white paper. Our aim was to identify launches which were exceptional within a country, using three quantitative criteria, and then develop a list of launches which were excellent internationally, i.e. consistently out-performed on our quantitative criteria across countries. The three quantitative criteria were:

- **A steep and sustained launch uptake curve.** We analysed the uptake curves of all launches in a country in terms of therapy area market share. Using a cluster analysis, we identified the launches with the steepest sustained uptake curve characteristics with that country. Thus, the market access environment of the country is taken into account, and we identify those launches which excelled regardless of market access restrictions.
- **Promotional out-performance** – we established the typical relationship between share of voice and market share within therapy class for each country, and then identified those launches which achieved high market shares with average or below average shares of voice. Again, we are searching for what is outstanding in the context of each country's specific promotional environment.
- **Market share achievement.** Excellent launch means rapidly achieving high market share ranking, within therapy area and by country. Excellent launches can accomplish this even in the face of substantial promoted competition.

Frequently, in order to achieve outstanding global success in launch, you need to be big, even though the market has opened up more to smaller players than in the era of Launch Excellence 1. As Figure 6 shows, a total of 118 companies launched 360 different new brands across the 8 countries in our study in the period between Q4 2011 and Q1 2015. Only 19 of these companies (16% of total) were behind the 31 excellent launches (9% of all launches).

Figure 6: Achieving global excellence in launch is restricted to a small group of companies



Notes: Companies and products are counted once regardless of the number of markets in which they are launched.

Sources: European Thought Leadership Launch Excellence V model;

While the top 10 companies launched nearly half of the globally Excellent drugs, mid-sized companies also launched a sizeable proportion. This reflects the shift to specialty products and the overwhelming importance of a small number of developed countries to the early sales of innovative protected products, meaning:

1. Small numbers of specialist healthcare professionals are the primary target for promotional activity rather than huge numbers of primary care physicians. Sheer scale of rep force, the killer app of the 2000s major pharmaceutical company, is no longer an advantage, although the smaller customer facing teams will need to be more multi-functional and sophisticated in their approach.
2. 86% of early innovative launch sales are made in just seven countries. The emerging markets contribute little to the early sales of protected innovative agents and this is likely to continue. An extensive emerging markets presence is not needed for successful launch.

Medium to small companies therefore operate on a much more level playing field with the biggest companies in today’s launch environment. They may even possess advantages – we have seen throughout our Launch Excellence series that one of the most fundamental differentiators between poor and Excellent launches is focus and alignment of the organisation behind the launch. This is often easier to achieve naturally in a smaller company with fewer, or perhaps no, other portfolio distractions. The downside of being a smaller launch company is the inevitable stretching of resources and lack, in some cases, of vital experience. Effective use of external partnerships and service providers can mitigate this.

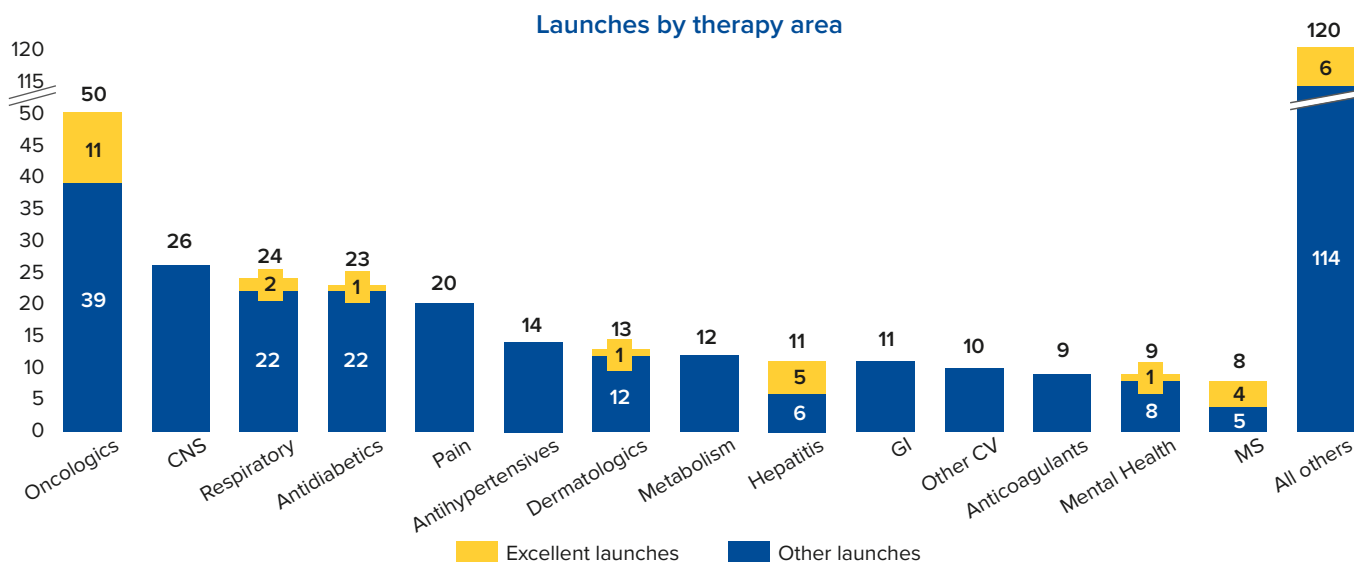


One of the most fundamental differentiators between poor and Excellent launches is focus and alignment of the organisation behind the launch.

Oncology leading the specialty ascendance but competition is tough

One therapy area in particular has been pivotal to changes in the launch environment since 2011 – oncology. As shown in Figure 7, it dwarfs other therapy areas in terms of number of launches.

Figure 7: More launches in a therapy area does not correlate with increased excellence – with the exception of oncology



Notes: Excellent launches are those achieving excellence in >1 country; Respiratory includes All Other Respiratory; CNS includes All Other CNS and Nervous System Disorders

Source: QuintilesIMS Thought Leadership Launch Excellence model

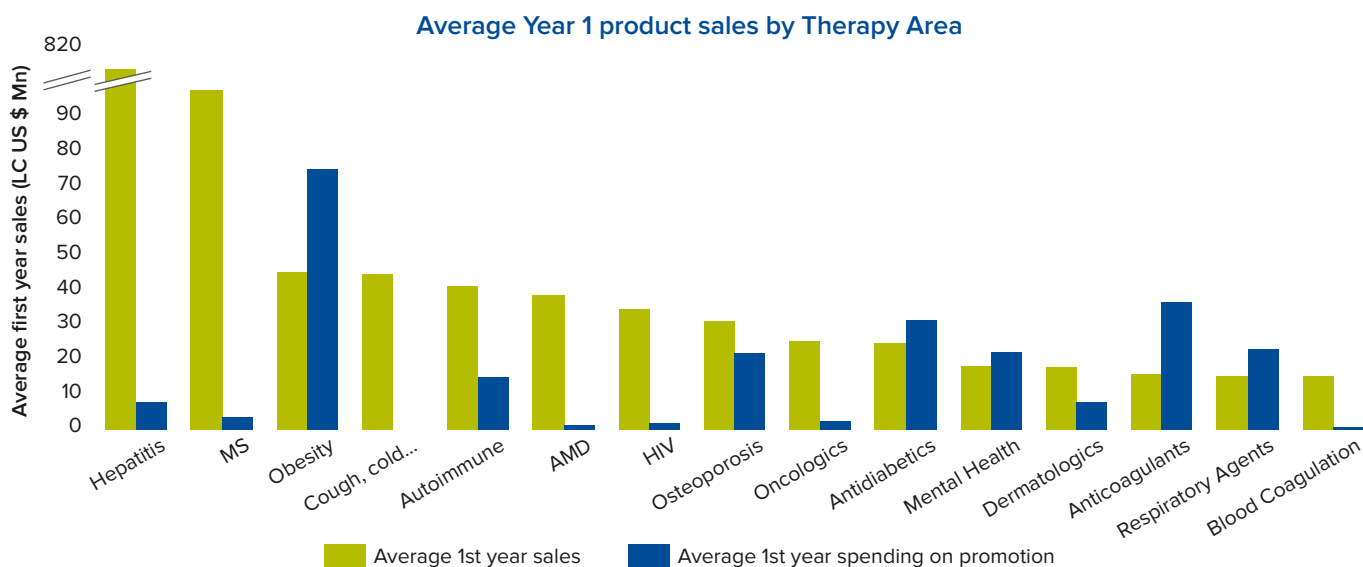
Molecular target discoveries and individually tailored therapies fragment cancers into numerous, sometimes orphan, indications, each a niche market with high unmet need. As a result, the last decade has been characterised by a wave of new drugs transforming outcomes for cancers with previously bleak prognoses – castrate-resistant prostate cancer and metastatic melanoma, for example. A total of 22% of new launches in oncology in the LEV period achieved global excellence (a better rate than all other fields save hepatitis).

These great steps forward have intensified the competition: differentiated efficacy (in oncology, survival) is harder to show against an evolving standard of care with lengthening survival times. Oncology drugs tend to enter the market first for the later-stage, sicker patients. Payers often prefer biomarker or diagnostic tests to ensure that they pay only for treatment of patients who are most likely to benefit from the expensive drug. These challenges may at least in part explain why the average first year sales of new cancer drugs (Figure 8) was lower than in other fields, including HIV and osteoporosis.

22%

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Figure 8: Promotional spending does not correlate with higher average first year sales



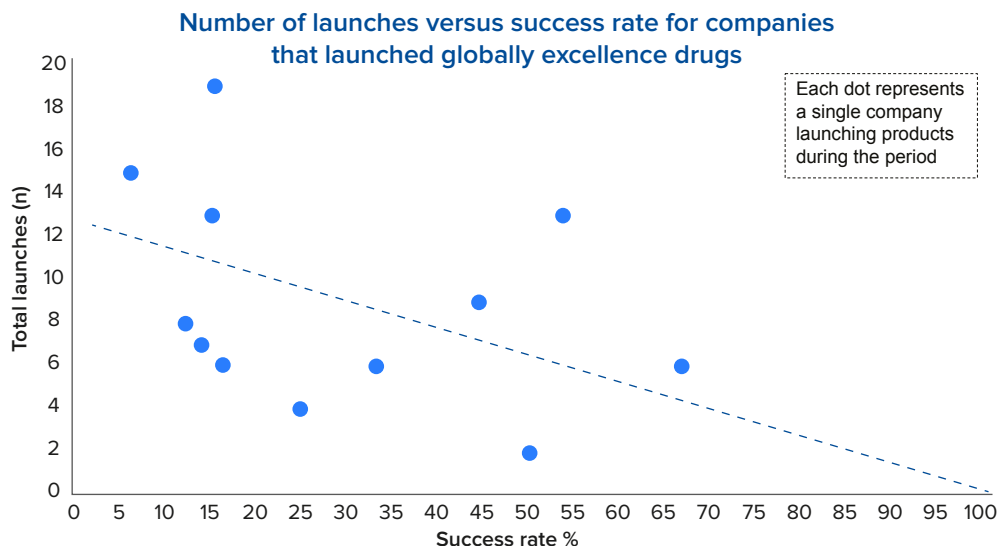
Notes: All launches within the period are covered, including excellent and non-excellent
 Source: QuintilesIMS Thought Leadership Launch Excellence model, QuintilesIMS Channel Dynamics

The challenges of high intensity launch

In our previous Launch Excellence studies², we’ve shown that the more launches a company executes, the lower the proportion of those Launches that achieve Excellence (Figure 9) – the reverse of what one might expect, if economies of scale or accumulation of learning were happening.

We found this inverse relationship once more with the new Launch Excellence V universe. It is a fundamental challenge that exists across companies, across launches and across time, and reflects the multifactorial complexity of a global prescription medicine launch. Bluntly, it is tough to launch a single product excellently. Doing so consistently for multiple, overlapping launches is even tougher. Companies struggle with the resource allocation, prioritization and split focus that high intensity launch demands.

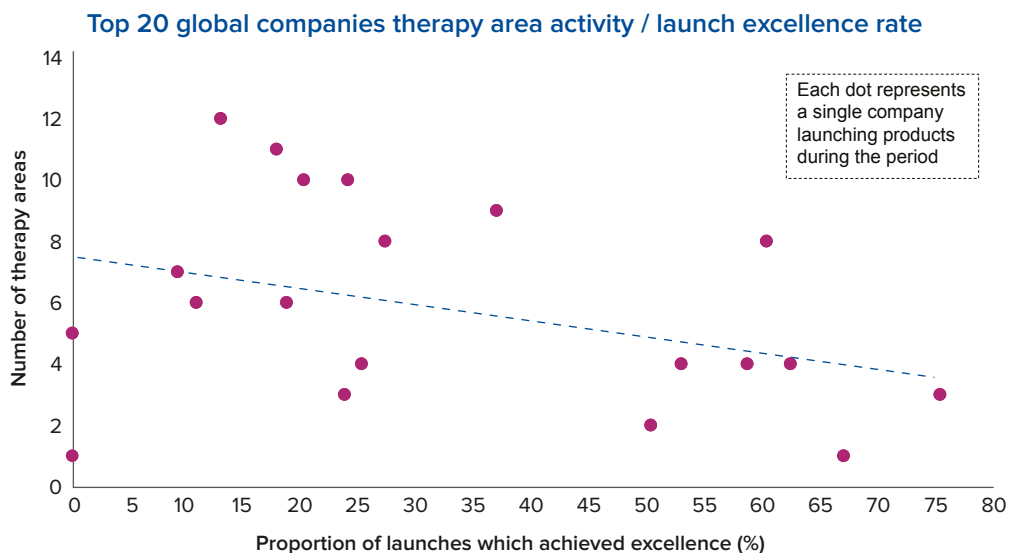
Figure 9: There is a negative correlation between number of products launched and excellence achieved



Source: QuintilesIMS Thought Leadership Launch Excellence model

In Launch Excellence V, we analysed this important phenomenon further. The number of therapeutic areas a single company launches in is a good proxy for increased challenges of complexity- the more therapy areas, the greater the complexity. There is an inverse relationship: those launching in only a few therapy areas achieve a relatively high proportion of excellence, while those that launch in many achieve a lower rate.

Figure 10: Only one of the top 20 companies that launched across >4 therapy areas excelled in more than half of launches



Source: QuintilesIMS

The Launch Excellence inverse relationship is a huge challenge for companies. Top 20 players cannot grow on a single launch; they need to launch frequently and fast. And while the move to specialty has focused many companies, the increasing competition means they cannot rely on one or two therapy areas. Even Roche, which has achieved greatness with its sharp focus on oncology, has diversified into new therapy areas in order to insulate against risk and provide consistent shareholder returns.

While no company has completely cracked the challenge of multiple Excellent launch, some companies are superior at overcoming it with careful and effective planning.

Johnson & Johnson – an exceptional Launch Excellence all-rounder

The prescription medicines arm of Johnson & Johnson, known as Janssen in Europe, achieved more excellent launches than any other company in LEV (and indeed in LEI). Janssen has entrenched a culture which has facilitated launch success consistently across decades and therapy areas. It continues to succeed as an all-rounder, launching products across primary care and specialty fields, from diabetes (Invokana) to lymphoma (Imbruvica).

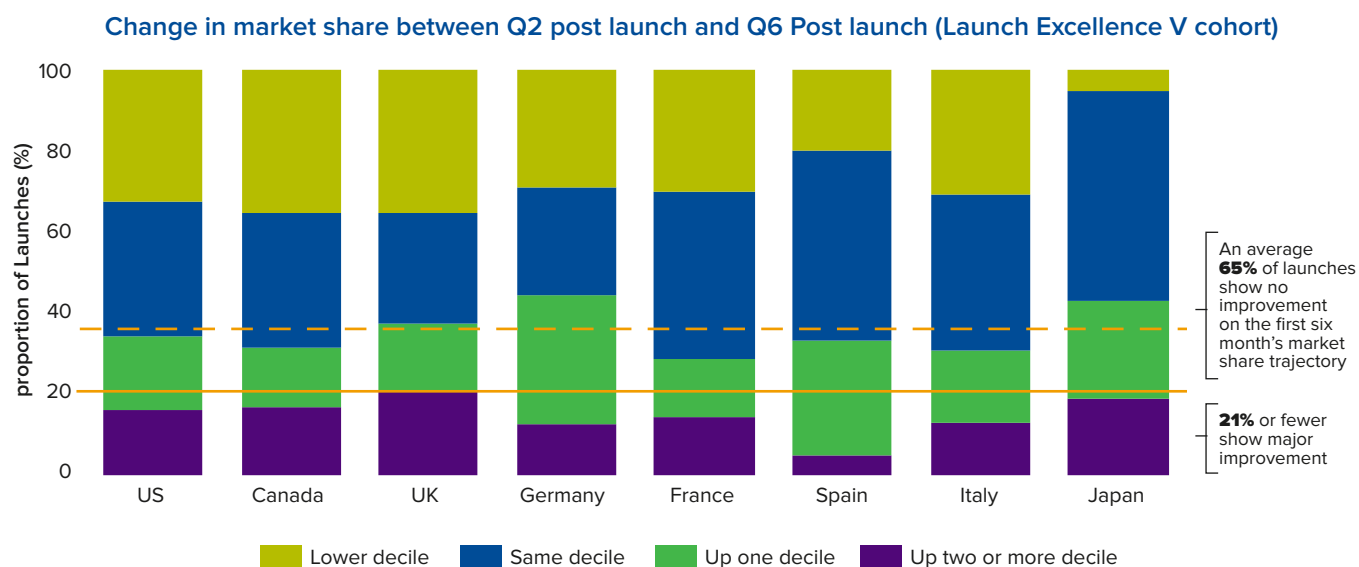
The company has been active in its patient-centric approach, with a high-profile mobile app platform (Care4Today) and initiatives to bring patient perspectives into clinical trials. J&J also seeks to “follow the science” to address areas of significant unmet need in global public health. This is backed up by our Launch Archetypes analysis – J&J launched more products than any other company in the Science Sells category.

J&J's exceptional track record is aided by a systematic approach to generating alignment behind the launch across countries and functions. A common launch playbook used across launches gets teams aligned from the start. Consistent tracking across countries enables transparent comparison of launch performance. Sharing of best practice across therapy areas, launches and countries means that Excellence can be identified and more widely adopted.

The six month window remains all-powerful

Perhaps the single most discussed, and sometimes controversial, observation of each of the Launch Excellence studies has been the speed with which the trajectory of the majority of launches is established. We have followed this by deciling market share achievements by quarter and by country, and noting whether launches shift their decile position over time. In every launch cohort there are undoubtedly launches which do make significant later improvements on the market share decile they find themselves in, at six months from launch. However, they are rare- 21% or fewer of all launches in that cohort, excellent or otherwise. On average, as shown in Figure 11, most launches will stay in the decile they established at six months, or decline.

Figure 11: Most launches still do not improve on their first 6 months



Source: QuintilesIMS Thought Leadership Launch Excellence model; QuintilesIMS Midas

If launches remain on the trajectory that they established and that trajectory was very strong (as it will have been for some excellent launches), this consistency is no problem. It is, however, very much a problem if a promising launch starts slowly. Precedent says you can turn the launch around – up to 20% of launches do. Prudence, however, says plan and prepare so you do not have to be in that situation – 80% or more of launches won't be.

Shifts in the commercial model for Excellent launches

The dramatic shift in healthcare spending towards specialty drugs is not reflected in the promotional spending dynamics: it is still more expensive to promote drugs in primary care markets with larger patient populations and doctors.

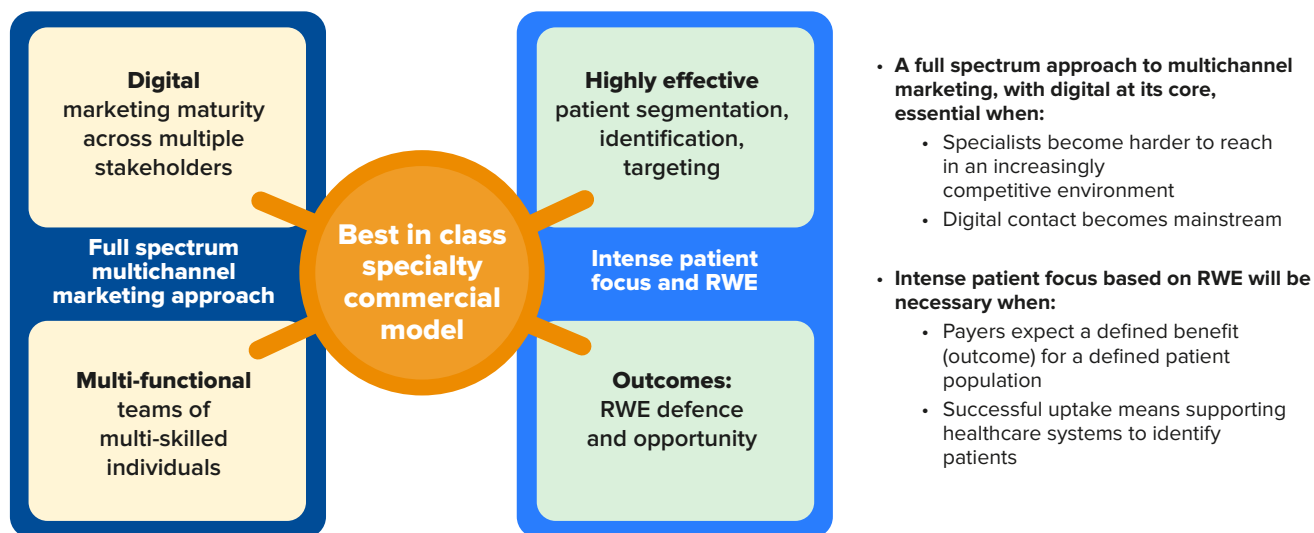
From a promo spending perspective, specialty drugs have much better margins. As a result, the areas in which most promotional dollars were spent (respiratory, antidiabetics) were not those with the highest sales in their first year on the market.

As more launches enter specialty therapy areas, these areas become much more competitive. Companies will need not just to have a specialty commercial model, but a best in class one in order to succeed. Figure 12 outlines the key elements of this new model:

- Companies will need to have a mature multichannel model, and a customer team which is fully integrated and enabled within it. As we will see in the next section, there’s evidence (but it does not imply causation) that Excellent launches have a higher share of digital activity in their early launch promotion. Certainly, when addressing small numbers of highly important but difficult to engage specialists, it is crucial to ensure that all channels are used to their best effect.
- Companies will also require intense patient focus. Specialty treatments are mostly for relatively small groups of patients with relatively complex, difficult to manage diseases. Defining and enabling the identification of these patients and supporting their treatment to get the best possible outcome will be key for excellent launches.

In this era of complexity and differentiation, excellent will be about how best to identify and communicate to a small group of often disparate physicians and patients the value they will gain and how the launch product will support them.

Figure 12: What do companies need for an excellent commercial model for specialty launch?



Source: QuintilesIMS

Planning for where the ball will be: anticipating the future launch environment

Planning for the future launch environment is complex, speculative – and essential. In the following section, we examine key changes that companies must anticipate and prepare for, in the short and longer-term.

What is likely to remain the same: developed markets focus

First, some aspects of the launch environment are unlikely to change dramatically in the next five or even ten years. The developed markets will continue to be the dominant regions where almost all New Chemical Entity (NCE) launches make the vast majority of their sales. The few exceptions might be in disease areas with prevalence focused on emerging countries. This developed market focus remains because even in the boom years, emerging markets were a tiny minority of the sales of the typical NCE launch, and now, with many emerging markets struggling economically, the highly specialised NCE launches are even less likely to thrive.

If and when this does change, it may be because emerging market pharmaceutical companies start to launch their own NCEs. There have been one or two NCEs a year which originate in emerging markets countries, but to date these do not get launched in the developed world. This may change as emerging market pharmaceutical and life sciences companies become more active in R&D. It's even possible that "reverse flows" of technology from the emerging markets to the developed world will eventually surface. If so, this advance might be led by medical devices, where regulation is a less exacting barrier, than prescription medicines.

What is likely to change slowly: specialty focus for New Chemical Entities

We are unlikely to be at "peak specialty launch" yet, but already the specialty launches dominate in number, contribution to overall sales value growth, and "Excellent" launch rankings. Will this continue? Two observations suggest yet another change in the ten year horizon:

- Key established specialty areas are maturing, seeing increasing competition, both from on patent brands and lower cost biosimilars. Unmet need is much reduced, and prices fall with competition within brands and also from biosimilars. This in turn narrows the opportunity for new specialty launches in these areas to smaller patient groups with remaining unmet need, but significant price premia will be less likely.
- This turns R&D attention to specialty areas where high unmet need remains, but in parallel we expect refocus on primary care conditions, perceived as low unmet need due to existing, genericised, low cost treatments. The chronic and progressive nature of many conditions, combined with low compliance and increasing prevalence, means high, but hidden, unmet need remains. Pharmaceutical companies who can identify patients with clear unmet need, demonstrate value for those patients and justify incremental price over often low cost generic medications, will find new launch opportunities in these mature areas. The new biologics entering the asthma and COPD space may be a harbinger of how this will succeed.

What is likely to change rapidly: payer attitudes to launch and the need for innovative funding approaches

Sovaldi and Harvoni were more than just the largest, fastest and most successful launches of recent times; they also marked a sea change in the attitudes of many payers to budgeting for future launches. The issue with these launches is not lifetime sales, which is within historic ranges, but the concentrated period (one to two years) in which they absorbed hundreds to billions of dollars of healthcare spend.



Pharmaceutical companies who can identify patients with clear unmet need, demonstrate value for those patients and justify incremental price over often low cost generic medications, will find new launch opportunities in these mature areas.

Some countries, fearing similar future situations, now propose launch thresholds or upper limits on the expenditure in a given year on a single launch. The German government, after consultation with stakeholders, abandoned a proposed cap of Euros 250m on first year sales. However, at time of writing, England, still proposes a “budget impact” threshold of £20m for a new launch in any one of the first three years the product is on the market, with special measures if it breaches this upper limit. Since 2012, 24 launches in the UK would likely have risked breaching that upper limit.

There’s a fundamental tension between pharma launch expectations and those of healthcare system payers: companies want rapid return on the hundreds of millions to billions of dollars research and development they have invested over many years. Healthcare payers prefer medicines budgets to grow slowly and predictably. They dislike sudden, significant incremental calls on budget.

Alternative funding approaches may be a way out of this impasse: could third party financiers provide an upfront payment to pharma in return for a longer revenue stream of smaller payments from the healthcare budget? Could differential payments by indication for the frequently multi-indicational specialty Launches target the return on investment to real incremental value? Could slower “soft launches” - where the product enters the market earlier in clinical development but grows use more slowly and in response to real world data feedback, soften the impact? QuintilesIMS expects radical changes to future pharma/payer discussions on launches.

What is likely to change rapidly: the impact of digital technologies, and multichannel, on launch

In the last five years, digital channels’ role in pharma’s commercial model grew significantly. We already see the impact on Launch Excellence. Nevertheless, multichannel has a long way to go before it is fully mature globally; even in the developed regions most European countries lag the US and Japan. We expect future commercial models will be much more sophisticated, with an orchestrated approach to customer engagement. Optimising the impact of a multichannel approach will be the new differentiator for Excellent launches.

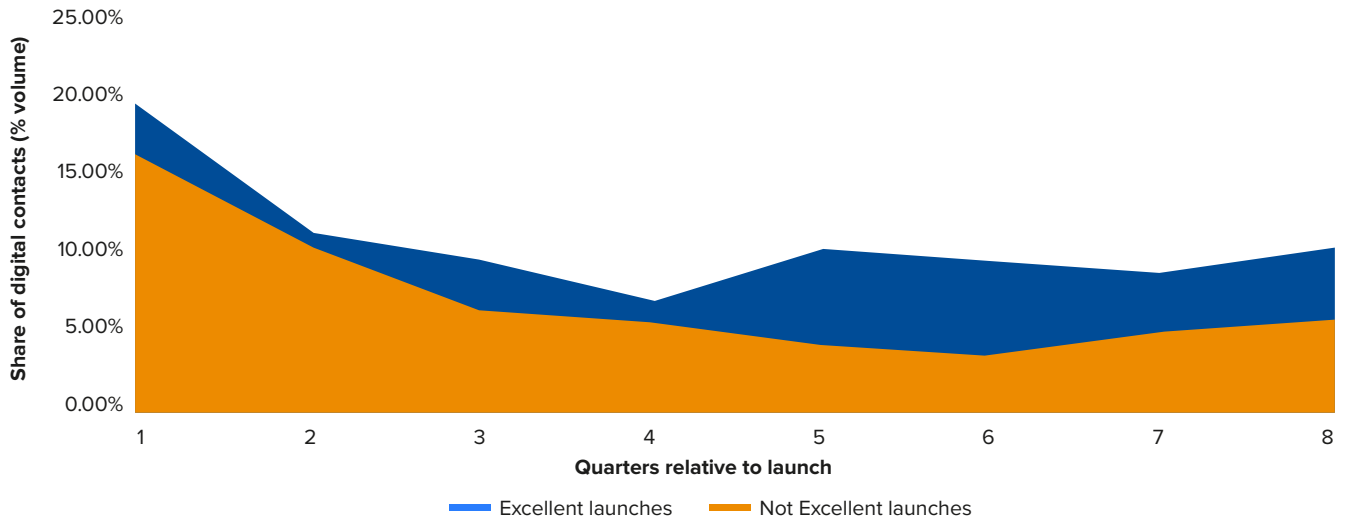
Multichannel implies a choice between a range of channels. Therefore, while digital is not multichannel in itself, mature multichannel requires effective digital. When we compared Excellent and non-Excellent launches in terms of the digital share of promotional activity, the profile of share change was similar – digital started at between 16-19% of all promotional volume and then trended down to between 9 and 14%. But, crucially, as shown in figure 13, for Excellent Launches, digital’s share of all launch promotional activity started higher and continued higher. We expect this Excellence observation will encourage further investment in digital for Launch across the developed markets. Turning that investment into an effective orchestrated, multichannel customer experience will be essential to future Excellent launches.



QuintilesIMS expects radical changes to future pharma/payer discussions on launches.

Figure 13: Launches achieving excellence have consistently higher share of digital promotion during first 2 years

EU5 + US + CAN – Recent launch volume share of digital promotional contacts



Notes: Recent launches=products launched after Q3 2011

Source: QuintilesIMS Thought Leadership Launch Excellence V, QuintilesIMS ChannelDynamics

What could change fast but is highly uncertain: regulatory change in the US and Europe

Two macro political changes of 2016, the UK’s decision to leave the European Union and the election of President Trump, have implications for European and US regulatory systems and therefore for the future of pharmaceutical launch.

The UK’s plans to leave the European Union by around 2019 inevitably create change for European launch approvals because the European Medicines Agency, currently located in London, must move to a European Union country. What is less certain is the impact of the change. It is possible that this move will disrupt the approval of new launches in the EU; the UK currently undertakes a significant percentage of the EU workload on new drug approvals. Disruption would change the paradigm of EU5 importance within the seven countries accounting for most of early launch sales, but it is unclear whether other countries would fill the gap created.

If the UK develops a separate regulatory system to the EU, a potential upside is freedom to develop a more attractive regulatory approach with faster approvals, and perhaps innovation, for cutting edge technology platforms such as gene editing and cell therapy. However, a risk is that regardless of regulation, the UK’s reputation as a challenging market for access persists, and as under 3% of the global market and 2.2% of the sales of NCEs in their first five years, it loses launch importance when outside the more significant EU4 bloc (15.1% of first five year sales).

President Trump has, so far, been top level on his plans, but has promised to cut 80% of FDA regulation. Whilst it is not clear how much would relate to drug approvals, as the FDA has a much wider regulatory remit, Trump has indicated his plan is for faster, more basic, safety focused drug approval with a greater emphasis on efficacy evaluation post product launch. The potential impact of this is a surge in drug launches in the US, and in parallel with an EU slowdown for the factors described above, would

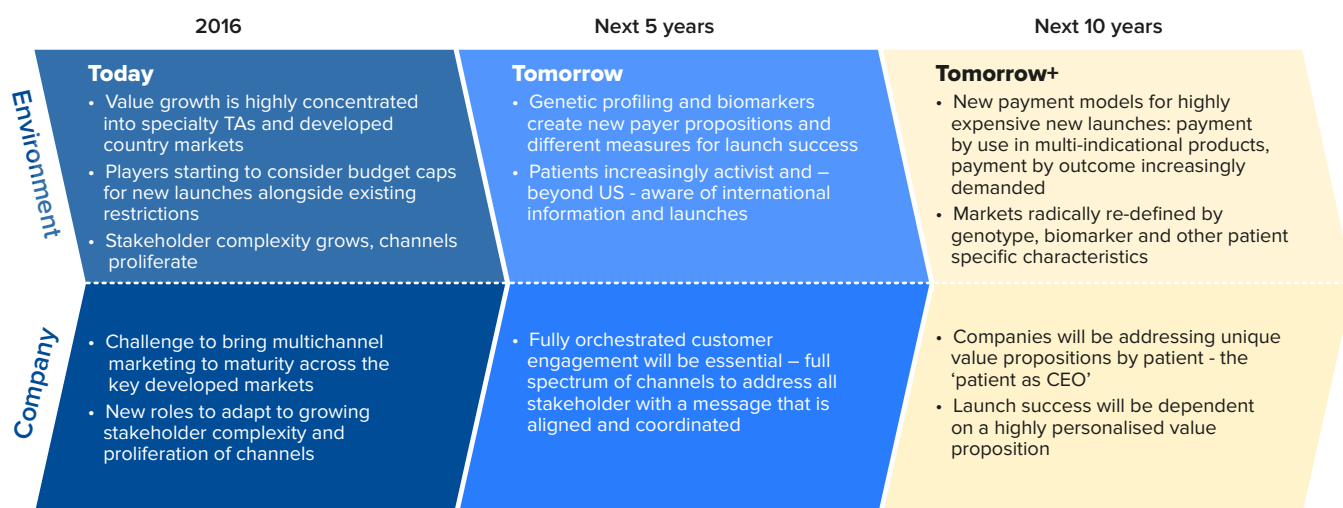
80%

President Trump has, so far, been top level on his plans, but has promised to cut 80% of FDA regulation.

make the US even more important to early global launch sales. However, there are risks. If launches enter the market without the full efficacy data currently required, then payers (and ultimately employers and patients) are effectively paying for these efficacy evaluations, and, if the launches prove less effective than promised, money will be wasted. If payers then prove reluctant to fund launches with a stripped down data package, the paradoxical effect of slashing regulation would be a slowdown in launch uptake. That is, of course, unless pharmaceutical companies take on the risk and lower prices, at least initially.

As Figure 14 shows, the Launch environment has changed hugely; it will continue to do so. Companies must anticipate the changes and ensure their functions, skills, capabilities and activities are fit for the environment their launches *will* face, not *would have faced*.

Figure 14: The launch environment has changed, and rapidly – companies must change too



Source: QuintilesIMS

Our Launch Excellence series consistently highlights three “foundational success factors” for Excellent launch: a powerful and pertinent value proposition, effective and efficient stakeholder engagement, and above all, an aligned organization behind the launch. Our Launch Excellence V research confirms the continued importance of these obvious, but in practice extremely challenging, success factors. In addition, we believe there will be new skills and capabilities companies will need for future Excellent launch.

Exceptional patient insight

- **In-depth understanding of the patient journey** – leveraging insight to overcome bottlenecks and barriers to treatment, to define the target patient groups and identify the stakeholders and influencers for that group, as well as to develop patient-centric programs enhancing experience and outcomes
- **Real-world insight and data** to demonstrate value and outcomes for payers; this may be part of a patient access or novel funding agreement
- **Key performance indicators which are patient focused**, giving leading edge insight into how patient activity and experience impacts launch performance

Cost effective and highly responsive commercial model with orchestrated, multichannel customer engagement

- **Competition has rocketed:** the focus has narrowed in terms of key countries and key therapy areas (specialty) while the number of companies wanting to play in this developed world specialty space has grown. This means huge competition for budgets, healthcare professional attention, and patients. Launch commercial models must engage across stakeholders and channels, rapidly, effectively, and with seamless coordination, and respond to competitive and environmental change. This will require a different order of orchestration to that currently seen.
- **A more diverse, but more coordinated, commercial team.** Medical Science Liaisons, specialist sales representations, Key Account Managers and other roles will become more involved with the overall orchestration of customer engagement. All roles must embrace a multichannel approach to working; digital technologies must be integrated, not separate.

A mutually beneficial re-set of the payer partnership

Future Excellent launches must create more innovative payer partnerships and funding approaches. There will be no single route to success. However, all companies must take into account these key principles:

- **Presume that your launch will be one of many competing for a limited budget.** Demonstrate why your product, rather than another, should access that budget. Increasingly, a second vital step will be demonstrating where budget can be saved in order to free up resource for a new product.
- **Payers are not just concerned about overall cost of new agents** – the speed with which that cost impacts healthcare budgets can be as crucial. Companies will have to think about the timing of their product's budget impact, and may need to agree approaches which manage that to achieve their launch objectives.
- **The real-world evidence collection and value debate on the Launch will start earlier** (even pre-Approval if commissioning through evaluation/early access to medicines schemes become widespread) and go on longer – right through launch to product maturity.

Continued emphasis on alignment

The most fundamental foundational success factor remains alignment of the organisation behind the launch, across countries and across functions.

- **Movement to specialty** drives internationalisation of information and dialogue- messages for the launch must be aligned, internationally and across audiences
- **Rise of competition in specialty:** rapid and coordinated competitive responses required
- **Innovative new approaches** such as multichannel, social media and patient centricity: international coordination required

True alignment means alignment on objectives, across functions, countries, and between international and local. It means agreement on strategic objectives and critical success factors for product, the critical success factors and the Key Performance Indicators to measure these.

QuintilesIMS experience suggests the majority of companies believe their launches are behind where they should be in preparation- but some of these launches will still be Excellent, and some won't. Superior alignment and focus on the issues that are at the heart of launch success makes the difference, and will also be key for future Launch Excellence whatever the challenges lie in store.

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