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Launch Excellence IV: a new launch environment

Planning for excellence in an environment of change

In the last decade, the pharmaceutical industry has seen extremely rapid changes in the environment for new launches. Understanding how the environment has changed and what this means for today's launches is a vital launch preparation activity.

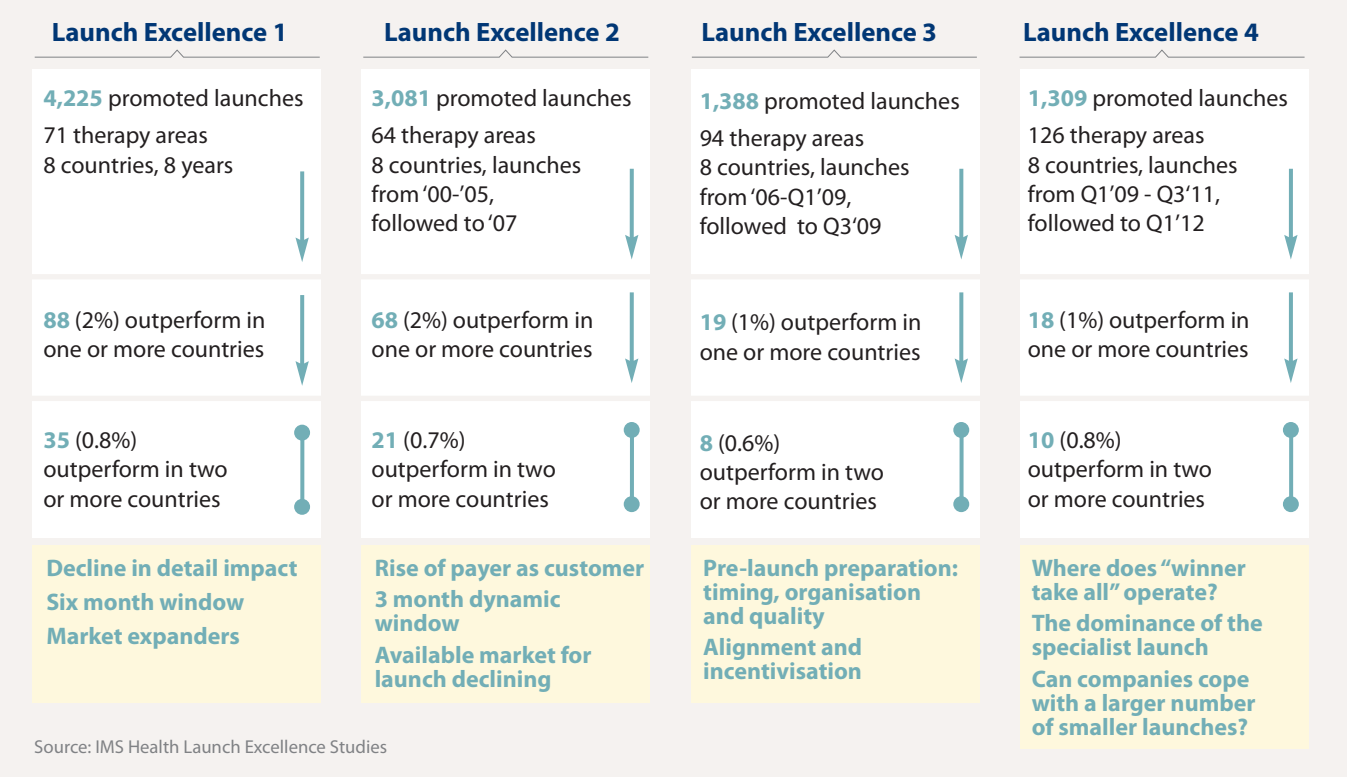
Introduction

Products in Phase II and early Phase III will enter the launch environment of up to five years from now. The current pace of change in the launch environment means that it is certain that it will have changed again. Strategic decisions about products in Phase II and early Phase III will affect the preparedness of the product when it launches in the 2015-2017 timeframe, and success or failure for the product could be built into its preparation very early. It's crucial to understand the current launch environment, the pointers to the future launch environment, and make a future perspective underpin all strategic launch planning.

In the landmark series of Launch Excellence studies, IMS has investigated the changing launch environment across major mature and pharmerging markets since 1997, undertaking detailed quantitative and qualitative investigations into the behaviours of the majority of launches, how performance varies between countries and over time, changes in launch drivers, and crucially which launches excel terms of outstanding performance relative to usual behaviours, and why. Understanding both longer term trends and recent dynamics is a crucial element of predicting future launch environment, and predicting future launch environment is a critical first step to planning to excel in it effectively.

With Launch Excellence IV as the latest in the Launch Excellence research program, IMS has completed a total of over six years of research on the Launch environment, covering more than 15 years of launches (since 1997) across eight countries which represent over 90% of all recent NCE (New Chemical Entity) launch opportunity in the world's top 16 country markets. We have investigated all primary care therapy areas and the majority of specialist care therapy areas, including, in this Launch Excellence study, oncology launches evaluated by a separate method. We have also, in Launch Excellence IV, extended our perspective beyond the lead eight mature and into the key emerging markets of China, Brazil, Turkey, India, Russia and Mexico.

FIGURE 1:
IMS HAS UNDERTAKEN FOUR MAJOR STUDIES ON LAUNCH ACROSS ESTABLISHED MARKETS



Source: IMS Health Launch Excellence Studies

In Launch Excellence IV, excellent launches have again been identified using three criteria of out-performance, versus the individual country norm:

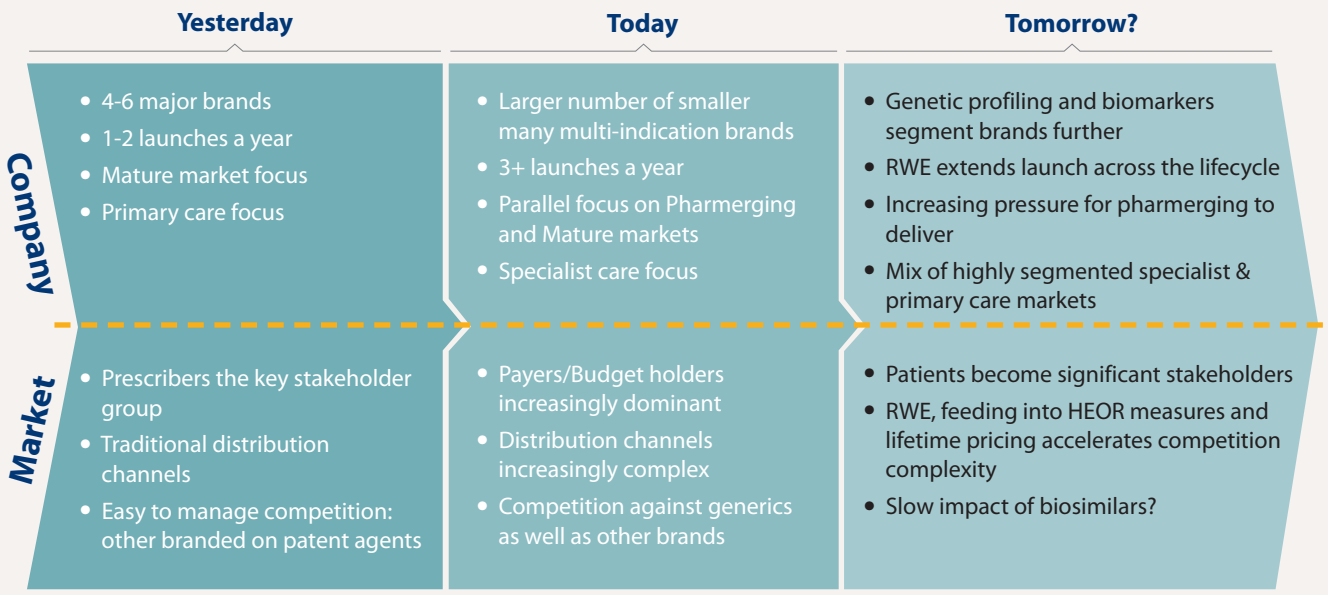
1. market share achievement relative to cumulative share of voice promotional investment to prescribers
2. market rank achievement – becoming a market leader in a short space of time
3. a superior profile of launch uptake curve.

IMS does not intend that these three criteria be seen as the only criteria by which excellence can be defined; they are simply intended as straightforward, quantitative criteria relevant to launch success which can be applied across a wide range of launches. As they have been applied in all four Launch Excellence studies, there is an unparalleled opportunity to compare across countries and over time to understand how launch environments have changed.

For further details on the Launch Excellence methodology, please see the appendix to this white paper.

THE LAUNCH ENVIRONMENT IS CHANGING RAPIDLY

FIGURE 2: THE LAUNCH ENVIRONMENT IS CHANGING RAPIDLY IN A MULTI-FACTORIAL FASHION



Source: IMS Health Launch Excellence Studies

As figure 2 describes, launch environment has changed, both for companies and in terms of the market, in a very wide variety of ways.

Changes in launch environment divide into long-term trends that have, and will continue to shape launch environment over the source of more than a decade, the more recent trends that have come to influence the environment in the last 2-3 years, and nascent trends that will start to impact in next five years.

We have an unparalleled opportunity to compare across countries and over time to understand how launch environments have changed

LONG TERM TRENDS IN THE LAUNCH ENVIRONMENT

Over the 16 years that we have studied launches, there have been some dominant themes – the first is changing stakeholder power, in other words, the balance of power between the key decision makers who decide which launches get used widely in their target market and become excellent, and which do not, and fail.

Successive Launch Excellence studies document that, whilst still important in many countries, traditional representative promotion to prescribers has progressively become less impactful, when impact is measured ability to drive market share and the certainty with which market share will be driven by increases in promotional share of voice. Over the course of successive Launch Excellence studies IMS has documented the trend of decreasing impact of audited prescriber focused promotion. In IMS's first Launch Excellence study, all eight countries studied showed a measurable relationship between cumulative Share of Voice in promotion to prescribers and therapeutic market share achieved in a given country at a specific timepoint post launch. Now, there are three countries where that relationship no longer exists for the Launch Excellence IV tranche, and for the countries where the relationship continues to exist, it is much weaker than it previously was.

There's variance between countries; the UK is the most extreme example, where there's complete breakdown between the cumulative share of promotional spend a launch achieves in its early quarters in its therapeutic market and the market share it achieves in its therapeutic market. The driver behind this is simple: prescriber focused promotion can only be a clear driver of market share if prescribers are primary decision makers on whether launch products get used.

That prescribers have progressively lost their individual decision making power on use of launches, ceding influence to the payer, national and sub-national, is a well documented trend

THE RISE OF THE PAYER

That prescribers have progressively lost their individual decision making power on use of launches, ceding influence to the payer, national and sub-national, is a well documented trend with origins, for some countries like the UK, in the 1990s. The UK's National Institute for Clinical Excellence was founded in 1997 with the remit to make Health Technology Assessments (HTA) on new UK launches, pronouncing on whether products were cost effective enough to be used in the UK, and if so with what patients and in what line of treatment. Similar restrictions, whether overt in Health Technology Assessment (assessment, or less formal, have spread across countries, as payers became the first-line decision makers on launch use. High profile launches, well supported and by major pharmaceutical companies, such as Exubera and Caduet from Pfizer, and Rasilez/Tekturna from Novartis, failed to achieve their originally predicted potential as a result. Payers continue to extend their grip on new launch potential; AMNOG, brought in into Germany in 2011, turned that market from a free launch pricing environment into one where new launches are assessed for incremental value over existing treatment after a year on the market.

Value Based Pricing, due for introduction in the UK in 2014, promises to remove the last major free priced launch European country. International reference pricing ensures that the downward effect of these increased controls then fans out across Europe, so payers influence launch environments in countries beyond their boundaries.

As payers have become more powerful, with more sophisticated tools at their disposal to manage the cost of new therapies, the environment has also changed in their favour. Thanks to peak small molecule genericisation, there are more off-patent, low cost therapies available in more therapy areas than ever before. The availability of effective low cost alternatives gives payers two levers to contain costs:

- They can act to restrict the volume of patients for which a new product might be used, by encouraging prescribers to treat newly diagnosed patients with less expensive generic therapies first. This sequencing, which may be written into guidelines or encouraged by incentives to prescribers or patients, has the effect of reducing the patient population mostly available to new launches to second line or exceptional cases.
- They can benchmark the price and cost impact of new launches to that of generic alternatives, for example, with AMNOG a new launch's incremental benefit could possibly be evaluated over a generic treatment in arriving at a reimbursement price.

Pharmaceutical companies have to find new ways to work in increasingly restrictive payer environments. At a global level, this means ruthless focus on the demonstration of product value versus existing standard of care. In oncology, as an example, in major cancers served with existing modern therapies, focus is coalescing on overall survival improvements versus current standard of care of six months or more as the benchmark for new launches to gain an excellent start in the market.

Where decision making power is largely or wholly in the hands of payers, the relationship between representatives and who they interact with is now more complex. In countries where payer power is less absolute, representatives are still changing the nature of their role. In the US, for example, the sales representative still drives launch performance, although now less so, and there has been a big change in the role of the sales representative. During launch, representatives still need to build awareness, and provide the clinical information, but they also now need to focus on identifying the patient type that will benefit from the launch product, as well as possessing a thorough understanding of the managed care environment to get the launch product covered, and to lessen the economic burden to the patient.

The other trend reducing impact of audited promotion to prescribers is their **declining accessibility to, and active movement away from, traditional information resources**. Traditionally the pharmaceutical representative was an important, if not a primary, source of information on new launches for doctors. In most countries, however, representative's access to doctors has been progressively restricted by both regulation and medical culture. In addition, the rise of the internet and social media technologies mean that doctors (and patients) receive their information via other media and from different sources. Pharmaceutical companies have, of course, followed their stakeholders online. But whilst electronic media offer a wide range of new interactions, they are both a challenge to measure and uncertain in terms of impact.

The picture is, however, not a simple question of power moving in one direction from prescribers to payers. Certain prescribers still remain influential and in certain therapy areas they retain more influence – in fact, the strong shift of launch activity into the specialist (and often extremely specialist, even orphan) sector can be a countervailing factor. In addition, new stakeholders have appeared in the form of patients, who have rising interest in, and influence on, new treatment uptake, and payers themselves have changed, with power fragmenting to local players in some countries, or re-consolidating at a national level in some countries with extreme financial stress.

THE MOVE TO SPECIALIST

As the key primary care therapy areas in cardiovascular, gastro-intestinal, respiratory, and CNS genericise, the number of launches, and especially the number of excellent launches, in these therapy areas has reduced. Global value growth for protected products has moved decisively towards specialist products, with the sole major exception of type II diabetes, where both launches and value growth remain strong. This long term trend accelerates in the coming years as peak small molecule genericisation means that the world's leading products will become almost entirely specialist and biologic, and the focus of launch activity becomes increasingly specialist, focused on areas such as oncology, autoimmune diseases, multiple sclerosis, and others. More recently, within the trend to specialist launches, there has been a move towards increasing numbers orphan and ultra-orphan drug launches such as Kalydeco for a particular variant of cystic fibrosis affecting about 3,000 people worldwide, that is, the more specialist end of the specialist spectrum, although these products, because they are for very small patient populations, generally remain relatively modest in total sales.

The excellent launches, by IMS Launch Excellence definitions, for our Launch Excellence IV study reflect this switch to specialty. Of the 10 identified, only one, Januvia, is a conventionally primary care launch.

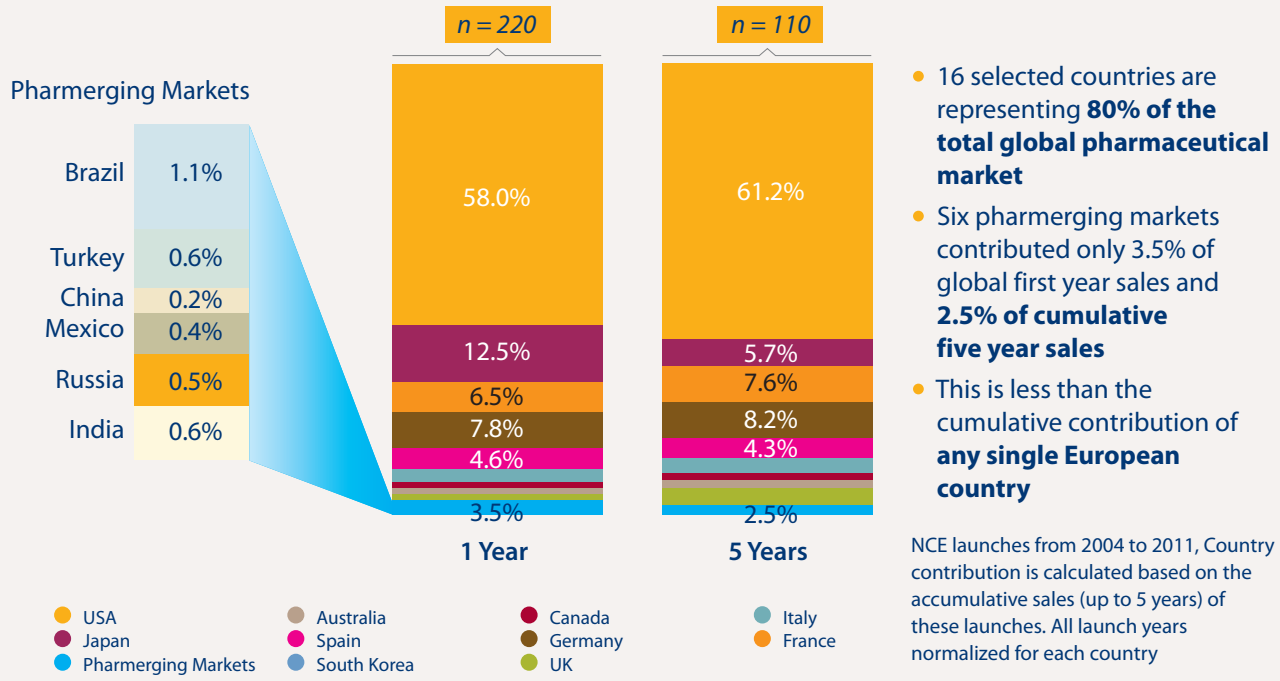
THE TREND THAT DIDN'T HAPPEN: NO MOVE TO PHARMERGING MARKETS

Over the past ten years, one of the dominant themes in the global pharmaceutical market has been the rise of emerging markets to a position of importance in terms of size, and value growth both for these countries and as a dominant driver for the value growth of the world's pharmaceutical market as a whole. Already, four of the world's largest country markets by value sales are emerging markets; to 2016 IMS expects almost two thirds of the entire global pharmaceutical market's value growth will be from pharmerging[1] markets, which will account for over one third of all global sales, by value, in 2016.

As the centre of gravity for global growth tips decisively in the direction of the pharmerging markets, it would be perfectly reasonable to expect a similar trend for the importance of pharmerging markets for NCE launches. This has not been the case. In fact, given their importance in terms of size and growth for global pharmaceutical market value, pharmerging markets significantly under-contribute to new launches. In our analysis in figure 3, IMS took NCEs first launched globally between 2004 and 2011, and analysed the contribution made to the cumulative sales of these agents by the 16 countries that account for almost 80% of current global pharmaceutical market value, in years 1,2,3,4 and 5 after launch.

[1] IMS has identified specific emerging market countries as pharmerging markets, on the basis of the importance, size and growth of their pharmaceutical markets. These markets are: Tier 1: China, Tier 2: Brazil, India and Russia, Tier 3: Algeria, Argentina, Colombia, Egypt, Indonesia, Mexico, Nigeria, Pakistan, Poland, Romania, Saudi Arabia, South Africa, Thailand, Turkey, Ukraine, Venezuela and Vietnam

FIGURE 3: LAUNCH IS STILL MOST OFTEN A MATURE MARKETS PLAY



- 16 selected countries are representing **80% of the total global pharmaceutical market**
- Six pharmerging markets contributed only 3.5% of global first year sales and **2.5% of cumulative five year sales**
- This is less than the cumulative contribution of **any single European country**

NCE launches from 2004 to 2011, Country contribution is calculated based on the accumulative sales (up to 5 years) of these launches. All launch years normalized for each country

Source: IMS Launch Excellence IV

Launches in pharmerging markets such as China are frequently much later than the US or Europe because of regulatory delay and launch schedule priorities, therefore we normalized all launch sales so that year 1 represented the first year sales of the launch in each of the countries, and so forth for subsequent years. When we did this we found that the six largest pharmerging markets, China, India, Brazil, Russia, Turkey and Mexico, accounted for just 3.5% of first year sales. At the fifth year of sales in each individual country, these same six pharmerging markets accounted for just 2.5% of the cumulative sales– less than any one of the five major European countries or Japan, and far less than the US (61% of the five year cumulative sales of NCE launches). NCE launches, in general, are still a mature markets play.

The reasons for the continued dominance of the mature markets for NCE launch as a whole are multi-factorial. Complex and difficult approval processes slow down launch and can dissuade companies from attempting to launch at all. Pricing and market access hurdles are also increasing in the largest pharmerging markets. The out-of-pocket nature of much or part of certain pharmerging markets means pricing must adjust to the more modest spending power of patients in these countries. However, the primary reason for the under-performance of these markets for launch is that the value growth of pharmerging markets is primarily driven by low unit cost generics, and innovative agents do less well. The leading 20 branded products in these pharmerging markets are all, without exception, over 10 years old.

There are exceptions to the rule that recently launched NCEs derive little of their sales from pharmerging markets. Launches in certain therapy areas – anti-infectives and diabetes are examples- are doing well in pharmerging. If we focus only on new diabetes launches for the analysis in figure 3, the 1 year contribution from the BRICTM markets for these products jumps from 3.5% to 10%.

However, in the next five years, IMS expects that for the majority of new launches, mature markets will continue to be the key focus for NCE launches. This is likely to be exacerbated by the growing importance of specialty launches. Most of these launches in oncology, autoimmune and orphan disease areas are very high unit cost products requiring sophisticated healthcare provision for effective use, and therefore unsuited to pharmerging markets.

In the longer term, 10-20 years, the under-contribution of the pharmerging markets to global NCE launch sales has to be successfully addressed by multi-national pharmaceutical companies. This will require careful selection of the right launches to prioritise emerging markets for, constant efforts to reduce regulatory hurdles, and close attention to appropriate price to market. We have seen this happen successfully for the new DPP-IV launches in diabetes, notably for Galvus, Novartis's DPP-IV launch, which did less well in mature markets than Januvia, but out-paced Merck's products in many of the pharmerging markets with a combination of rapid launch, promotional investment, and early use of local partners in certain markets, such as India.

Companies need to consider the core countries that they choose for their launches on a case by case basis: for some launches, perhaps especially specialist ones, it will still make sense for these core countries to be the mature markets. For other therapy areas, however, new countries will have to be prioritized to break out of what will otherwise be a self-fulfilling prophecy – "NCE launch is a mature markets play".

New trends in the launch environment

HIGHLY SPECIALIST AND SMALL TO MID-SIZED COMPANY LAUNCHES

In a previous white paper[2], IMS identified that whilst the benchmark sales level for a true blockbuster has risen over the years, the number of launches reaching that benchmark level has not risen, and may even be about to fall. Even with the "traditional" $1bn measure of elite status, the number of launches entering the $1bn club has fallen.

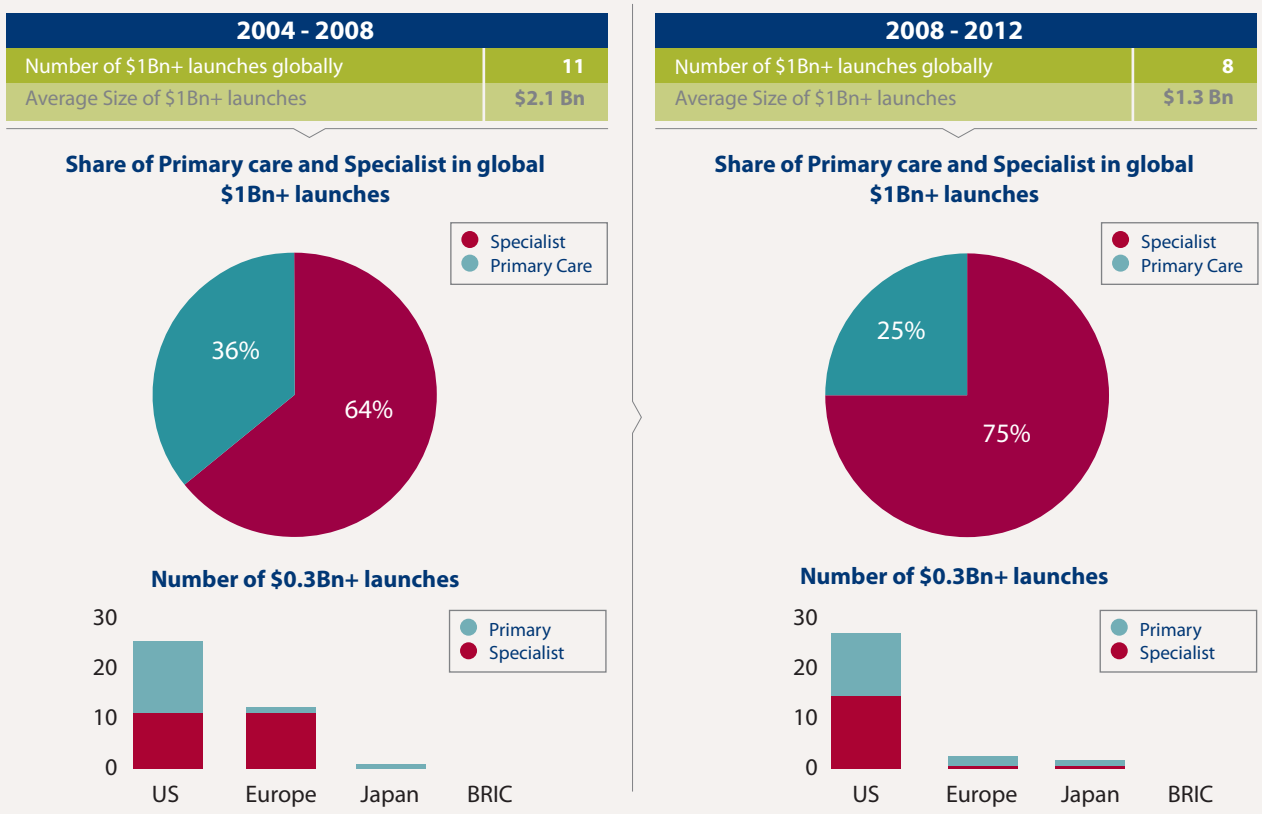
The current tranche of launches which meet the IMS Launch Excellence criteria show some strong differences to earlier groups of excellent launches. Already mentioned is the strong focus on specialist or specialist-lead launches; all the excellent launches, with the exception of Januvia, fall into this category. Even Victoza, which by size and performance in the GLP-1 category of diabetes agents is an excellent launch, is more likely to be specialist prescribed than the usual run of oral diabetes agents.

In addition to specialist dominance, the most recent excellent launches contain examples of very highly specialized launches, that is, launches for small patient population diseases treated only in the specialist environment, such as Lucentis for wet AMD, or Gilenya for multiple sclerosis (did not make Launch Excellence criteria, but is one of the recently launched products that has made it to $1bn+). Excellent launches are also coming from smaller companies – Incivek was the first launch that Vertex has done by itself (although it did use a partner, J&J outside the US) and Gilead has, with Atripla, an HIV medication which is an outstanding launch, become one of the leading HIV players globally.

[2] "Redefining the blockbuster model: why the $1bn entry point is no longer sufficient for defining true, elite blockbuster status" S Rickwood, 2012

These two emergent trends – for smaller patient population launches being excellent in both relative performance and absolute size and for small to mid-sized companies launching excellent and significant launches – are linked. Highly specialist therapies need neither the massive scale of clinical development nor the vast marketing and sales effort of a primary care or broad patient populations specialist drug. In addition, their main geographic opportunities will be in mature markets, since emerging markets frequently lack the funding and treatment infrastructure for these products, and in some cases (multiple sclerosis is an example) disease prevalence is not so high. Figure 4 shows how two tranches of launches, those from the period 2004/8 and those from 2008/12 compare in terms of the number of $1bn+ products produced by launches in this time period by the end of the time period, the average sales of the launches in the time period that made it to $1bn, the distribution of these major launches between primary and specialist care, and the geographic distribution of the group of "medium-large" $300m+ launches in each time period. A trend to more specialist, but also smaller launches, with a greater focus on the US, is clear.

FIGURE 4: RECENT MAJOR LAUNCHES HAVE BEEN MORE SPECIALIST DRIVEN AND SMALLER IN SIZE THAN EVER BEFORE

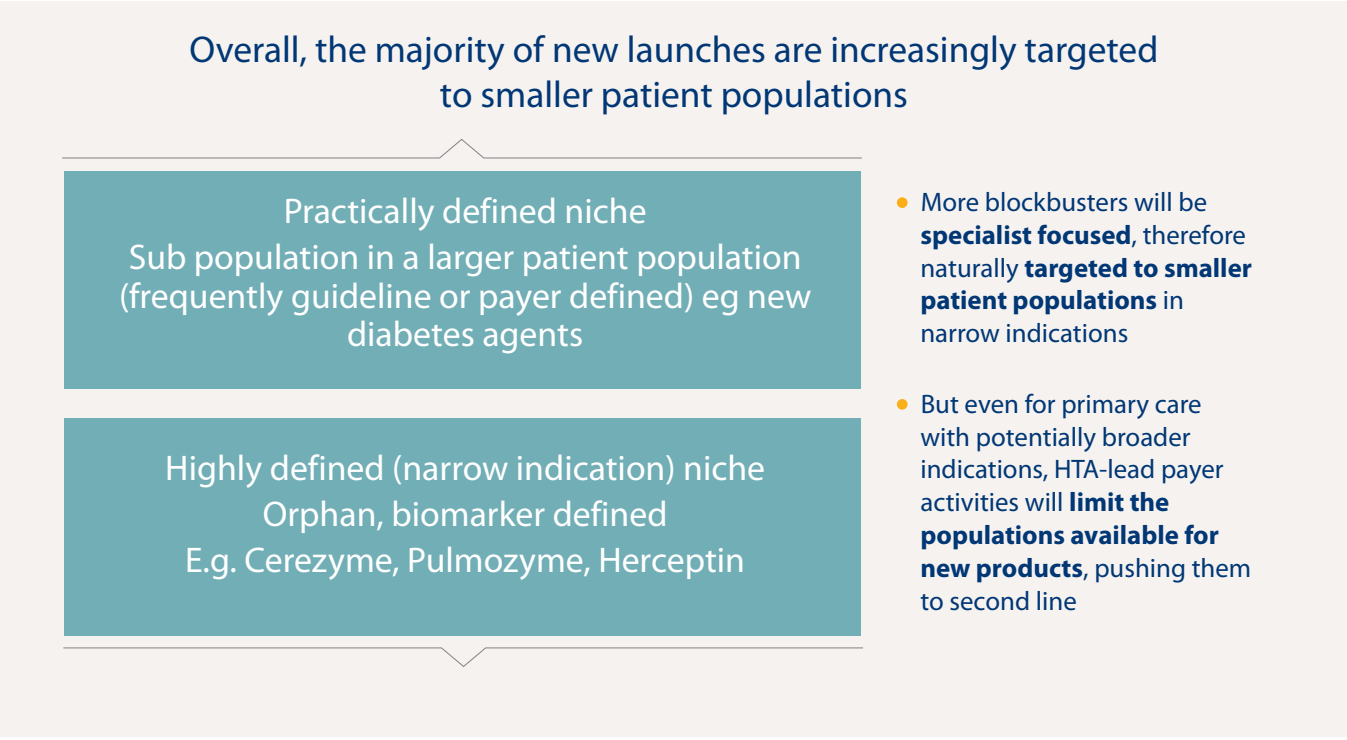


Source: IMS MIDAS 2012 Dec. The number of $1bn products and their average size is measured for each tranche at the end of that time period – i.e. 2008 for the first tranche and 2012 for the second

SMALLER LAUNCHES

Even excellent launches are becoming smaller in overall absolute size, in part a consequence of the more specialist nature of excellent launches, but also because of an overall trend to more defined patient populations for new launches. As noted in figure 5, greater numbers of products are for highly defined patient populations (orphan drugs, biomarker defined populations). In addition, there are increasing numbers of therapy areas for which launch patient populations become practically defined. This will occur where prior genericisations mean that there are effective and low cost therapies available multisource, as there are for the majority of primary care diseases, and an increasing number of specialty ones. In such circumstances, where cost constraints on pharmaceutical spending exist, low cost generics can be used as first-line treatment, as noted in an earlier section. This means that the first-line treatment market is either wholly or partially unavailable to launch products, even if they have a first line label. The available patient population is smaller for launches, in some case much smaller. Overall sales will, accordingly, be constrained. These effects have the impact of making primary care launches, in particular, struggle for excellence if defined as dominance of the full patient population, because the launch will only be able to enter part of the patient population, and uptake, if it is second line, may be slow. It also limits the overall sales potential of launches.

FIGURE 5: THE MAJORITY OF NEW LAUNCHES ARE INCREASINGLY TARGETED

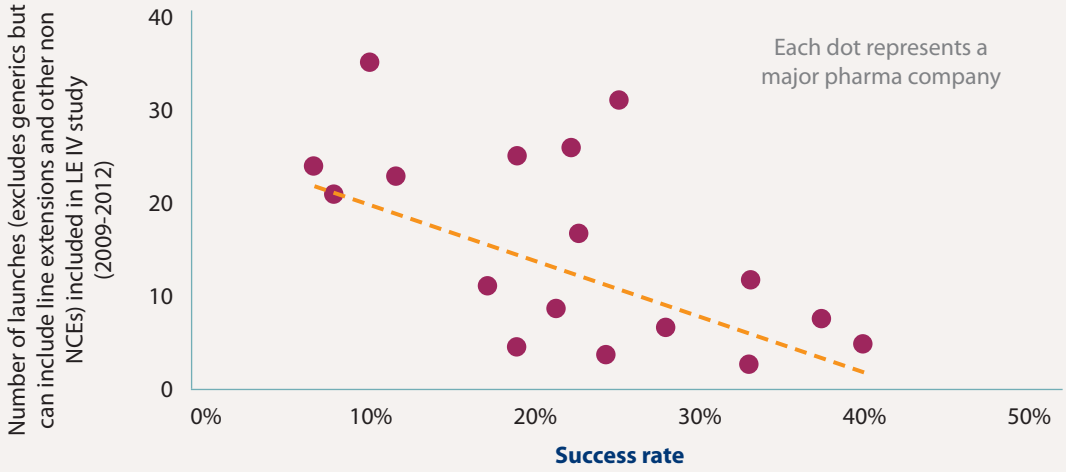


HIGH INTENSITY LAUNCH

The implications of this trend are worrying for major pharmaceutical companies. Smaller individual NCE launches means a larger number of launches in a shorter space of time will be needed to maintain or grow revenues. IMS Launch Excellence analysis suggests that the world's largest companies have, historically, been poor at converting high numbers of launches into high percentages of excellent ones. We analysed launches from major multi-nationals within the current Launch Excellence IV database and assessed their excellence by our Launch Excellence criteria. In addition, we assessed recent oncology launches by a simpler set of excellence criteria to include oncology launches. We found (figure 6) that the historic rule seems to have been that the greater the absolute number of launches a company has made, the lower the percentage that achieve excellence. This seems surprising, almost counter-intuitive in some ways, because we would expect companies to learn and improve with a high volume of launches. However, in reality, companies seem to struggle to achieve this, and instead experience the downsides of high intensity launch – lack of focus, resource allocation conflicts, and prioritization conflicts. Given that it is not just likely but necessary that companies will experience high intensity launch in the future, success will be dependent upon companies managing the challenges of high intensity launch and capturing the positive effectively. Historically, even the largest companies in the world, with strong resources behind internationally coordinated launch efforts, have failed to achieve this.

FIGURE 6: THE MORE YOU LAUNCH, THE LESS EXCELLENT YOU GET

The relationship between the number of non-generic launches captured in LEIV and the percentage of launches classified as successful by IMS launch excellence criteria



The percentage share of all non generic launches that were classified as excellent in at least one of the IMS excellence criteria (one launch can be launched across multiple countries)

Source: IMS Launch Excellence IV

The challenges of multiple launches in a short space of time are the negative impacts of a lack of resource, time and focus. Even when launches are in very different therapy areas, with separate business units at international level, it can be difficult to keep focus and adequate resource from sufficiently early on at a local level. Separate structures for different launches in the form of different business units can help to some extent, but are not an infallible solution, especially when multiple launches are within a business unit, as is often the case.

However, there are advantages to being in a high intensity launch situation – a large number of individuals acquire launch experience in a short space of time, and a huge quantity of learnings are generated from launch experience which can be used to help subsequent launches. Companies frequently fail to either recognise or effectively capture these positives in a systematic fashion.

Launches can improve on their first six months performance, but the majority don't.

THE CONTINUED INFLUENCE OF THE FIRST SIX MONTHS

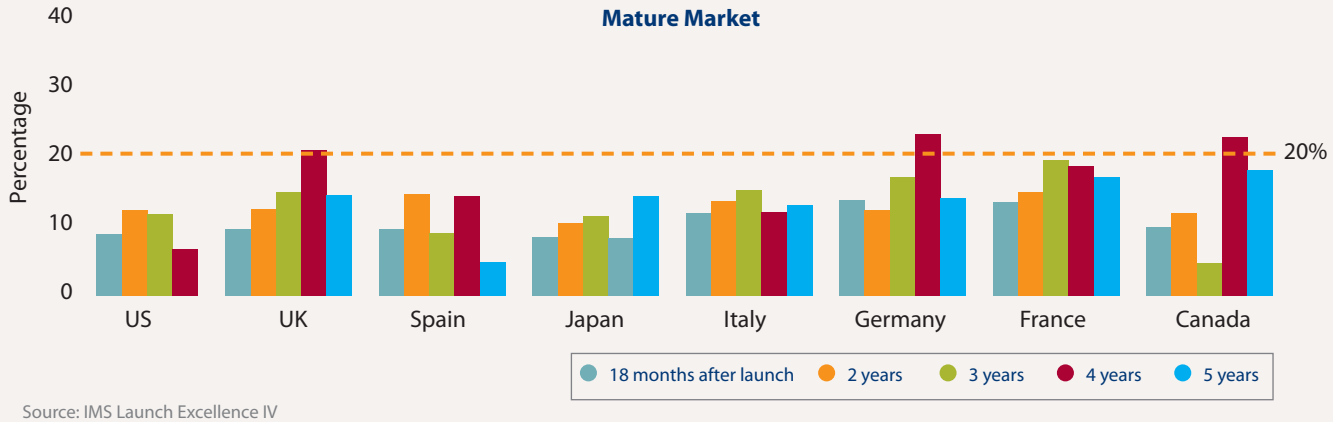
Successfully negotiating high intensity launch periods is particularly crucial, because of the high importance of a launch's performance in its first six months of sales on the market to the later performance of the product. IMS has analysed this issue in all of our Launch Excellence series, with a strong evidence base since 1997, on eight countries, and across a wide range of therapy areas, only excluding oncology. Consistently, we have found that the market share decile that a launch is in, at the end of its first six months on the market, is in 80% or more cases, not going to be exceeded by the end of the first eighteen or twenty four months on the market (see appendix for a detailed description of the methodology). In other words, launches can improve on their first six months performance, but the majority don't. Those that do, frequently have a major positive piece of clinical news in the period between six months and later – whether a new label or a major outcomes trial, or a significant gain in market access. In Launch Excellence IV, we extended this analysis out to five years into the market, to understand if the six month window is really a phenomenon of early launch – we found (figure 7) that is was not. Even as late as five years into launch, for the majority of launches, the product remains in the same or an adjacent market share decile to its place at six months. Launch fate is determined early, and only rarely overcome.

When we extended this analysis to key pharmerging markets, we found a different picture in two – while the six month rule held in all countries out to 18 months, in Turkey and Russia it is significantly exceeded at timepoints thereafter, although it is still a minority of launches that are making significant improvements. We believe this difference in behavior for at least some emerging markets is a function of the different stage of market development – therapy areas that would be mature and largely stable in mature markets are still expanding in emerging markets, and launches which would be largely market penetrative in mature countries can act as market expanders in emerging markets, and this can positively impact market share in the longer term.

FIGURE 7: THE SIX MONTH WINDOW INFLUENCES LAUNCHES OUT TO FIVE YEARS

In mature markets, the six month window rule persists up to five years out

- Only a **minority of launches make significant improvements** in their market share trajectory up to five years post launch
- **Early launch behaviours** have implications for launches for a very long period of time in mature markets
- Whilst it is possible to improve, most do not – hence, it is extremely important to plan to **get launch right the first time**



Source: IMS Launch Excellence IV

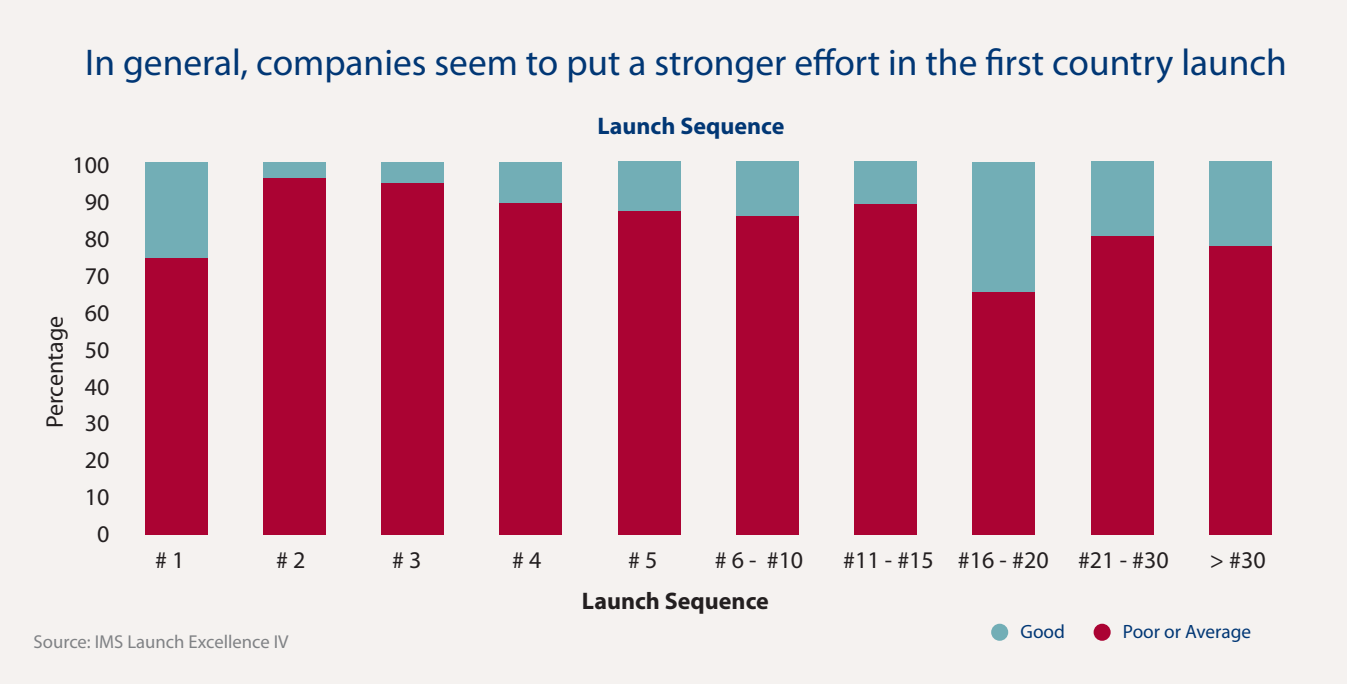
The implication of the extended impact of the first six months is simple, and crucial – companies have to prepare and focus in this exceptionally important launch period. This simple challenge is, in fact, very tough to carry out successfully even for a single launch, because of the disconnects that frequently exist between the different functions in a pharmaceutical company, between international and affiliates, and between the need to invest in the future with a focus on launches and the need to deliver on existing portfolio revenue and profitability targets. It's therefore likely to be even more challenging when companies have multiple launches to roll out in a year at global and affiliate level.

The implication of the extended impact of the first six months is simple, and crucial – companies have to prepare and focus in this exceptionally important launch period.

CONSISTENT PERFORMANCE ACROSS COUNTRIES AND LAUNCHES

Individually smaller launches mean that there will be less room for poor launch performance, because the very large blockbusters behind which some companies were able to tolerate surprisingly high levels of launch failure will no longer exist. Each launch will matter more than ever before, and for each launch each individual country launch will matter. Companies have to have the structures and processes to ensure better consistency across countries and launches. Evidence from Launch Excellence IV suggests that companies have not, historically, been good at maintaining consistency of performance across countries. We analysed the proportion of launches in each of the eight launch excellence countries that were good, average and poor, according to our excellence criteria, by the country's position in the launches' global launch sequence. It's worth noting that our launch excellence criteria measure launch performance in the context of what's usual in each individual country. We found that while the proportion of launches that were good in the first country of global launch was high, the proportion dropped dramatically for countries that were number two to number 15 in the launch sequence. Thereafter, the proportion of good launches rose again.

FIGURE 8: LAUNCHES ARE LESS LIKELY TO BE GOOD IN THE COUNTRIES IMMEDIATELY FOLLOWING THE FIRST LAUNCH COUNTRY



Source: IMS Launch Excellence IV

One obvious potential cause for this pattern could be the non-random distribution of countries along the launch sequence – launches are very strongly likely to enter the US market first, and the UK and Germany, historically free-priced countries, also feature frequently on the early launch country list. Conversely, Japan has almost always been a late launch country, and so, frequently, are Spain and Canada. Could this distribution of good launches simply be a function of it being easier to achieve a good launch in the US? However, when we removed the US from the analysis, we found a very similar pattern: the first country in the launch sequence was more likely to have a good launch; countries immediately following are less likely to have good launches, and then, for much later launches, the proportion that is good rises again.

In the context of our theme of focus and consistency, our conclusion is simple: the most likely cause of this pattern is the failure of companies to be consistently effective in getting the best out of all the countries into which they launch. It's unsurprising there's strong focus on the first country to launch, but that focus seems to waver when the launch is rolled out across the immediately succeeding countries. Given that launch countries two to fifteen are likely to include many or all of the countries with the greatest potential for launch, this is a failure which reduces overall launch performance. Again, companies must have a structure and process that ensures consistency of preparation and maximizes the change of optimal performance across all launch countries. Just as companies must leverage best practices and knowledge sharing across launches to optimize multiple launch situations, they should leverage knowledge across countries for any given launch, to ensure that consistency of performance is maintained across countries.

The future of launch: early launch strategy

A launch environment of more specialist launches, greater definition of patient populations, and a higher frequency of launches with a greater need for consistent success already exists. In the next five to ten years, we anticipate companies preparing products that are in phase III or earlier in the pipeline will also have to address additional challenges. These will include:

- Genetic profiling and biomarkers extending out of current areas of use, such as oncology, and becoming widespread in other therapy areas
- The revival of certain primary care markets with innovative launch entrants – facing the challenge of launch success in a satisfied and genericised market
- Real World Evidence taken to the ultimate conclusion of lifetime pricing and value assessment
- More, individually smaller launches encourage a change in how launch expectations are set, measured and managed. In addition, as a given, the bar for what is genuinely innovative and regarded by payers as having real incremental benefit will be continuously ratcheted upwards, as will the quality of the clinical evidence acceptable to regulators and payers.

Companies which succeed in the launch environment of 2018-2023 will be doing the following things now to ensure that their launch is ready for the environment of the future:

- Building an extremely detailed stakeholder map – specific to their therapy area and to their country, which highlights not only the current stakeholder environment, but the key changes that are expected and the events which will need to be watched which will change that stakeholder environment
- Exploring novel approaches to pricing and market access, including building in enough time for translating clinical data into convincing arguments to support early discussions with budget holders and authorities
- Creating a real world evidence plan alongside the pre- and post launch clinical development plan
- Considering the patient segments for the launch (including a rigorous assessment of the possibility of biomarkers), in order to set product performance expectations with investors and with payers

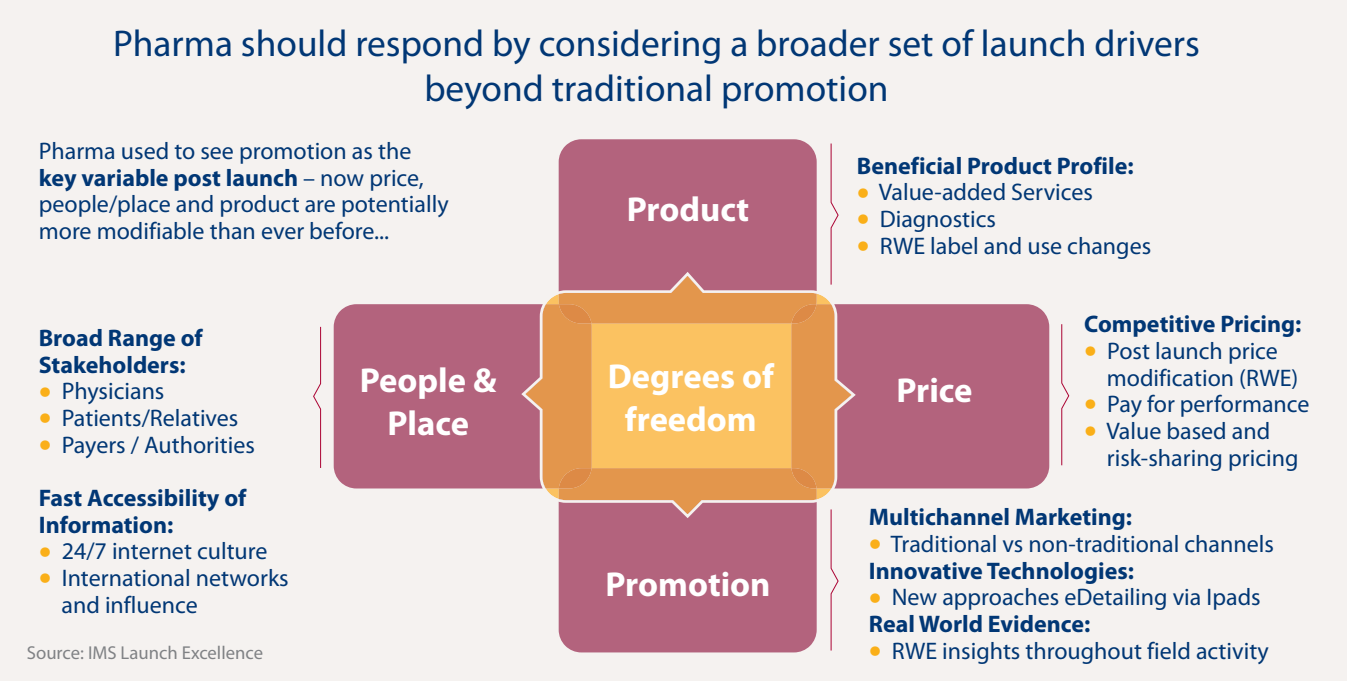
- Creating a comprehensive lifecycle management plan – assessing the opportunity for further indications, post launch clinical development, and value adds in service and product that build and strengthen relationships with stakeholders, including the patient.
- Establishing cross-functional teams earlier in the development process as this is key to a better understanding of optimization opportunities for the products in a market
- Rethinking the launch sequence and priority markets that provide the best potential for the product
- Understanding the clinical trial landscape, and KOL networks and optimize trial design to include key markets and clinical centres

In fact, companies really need to plan their early launches with the perspective that they have more degrees of freedom than they ever had before. The more complex environment, with more stakeholders, countries of importance, promotional channels and definitions of product and product value also brings greater opportunity for innovative approaches to product development and launch preparation. Trends that will enable a different perspective on launch, in some cases expanding what constitutes launch to a much longer time horizon include:

- Real World Evidence could extend some of the launch issues previously only addressed once across a product's lifecycle, specifically price and label, but also positioning and stakeholders
- New stakeholders and new technologies change the audience to be reached for launch and even the nature of the launch offering.

More than ever, companies must be prepared to discard their established approaches to launch, and ensure that they are preparing for tomorrow's launch environment.

FIGURE 9: COMPANIES HAVE MORE DEGREES OF FREEDOM TO LAUNCH THEIR PRODUCT THAN EVER BEFORE



HIGH INTENSITY LAUNCH: THE KEY CHALLENGE

More than ever, companies must seek to eliminate avoidable inconsistency in the execution of their launches, because every launch, and every country within a global launch plan, will count. This is a consequence of:

- The trend to a larger number of smaller launches in shorter spaces of time, in other words, a higher intensity launch environment, and
- An indefinitely restrictive launch environment in the European countries that constitute five out of eight key mature launch markets, meaning that, whilst these countries still continue to be very important to launch, companies have to seek ways to make other markets, such as pharmerging markets, matter more.

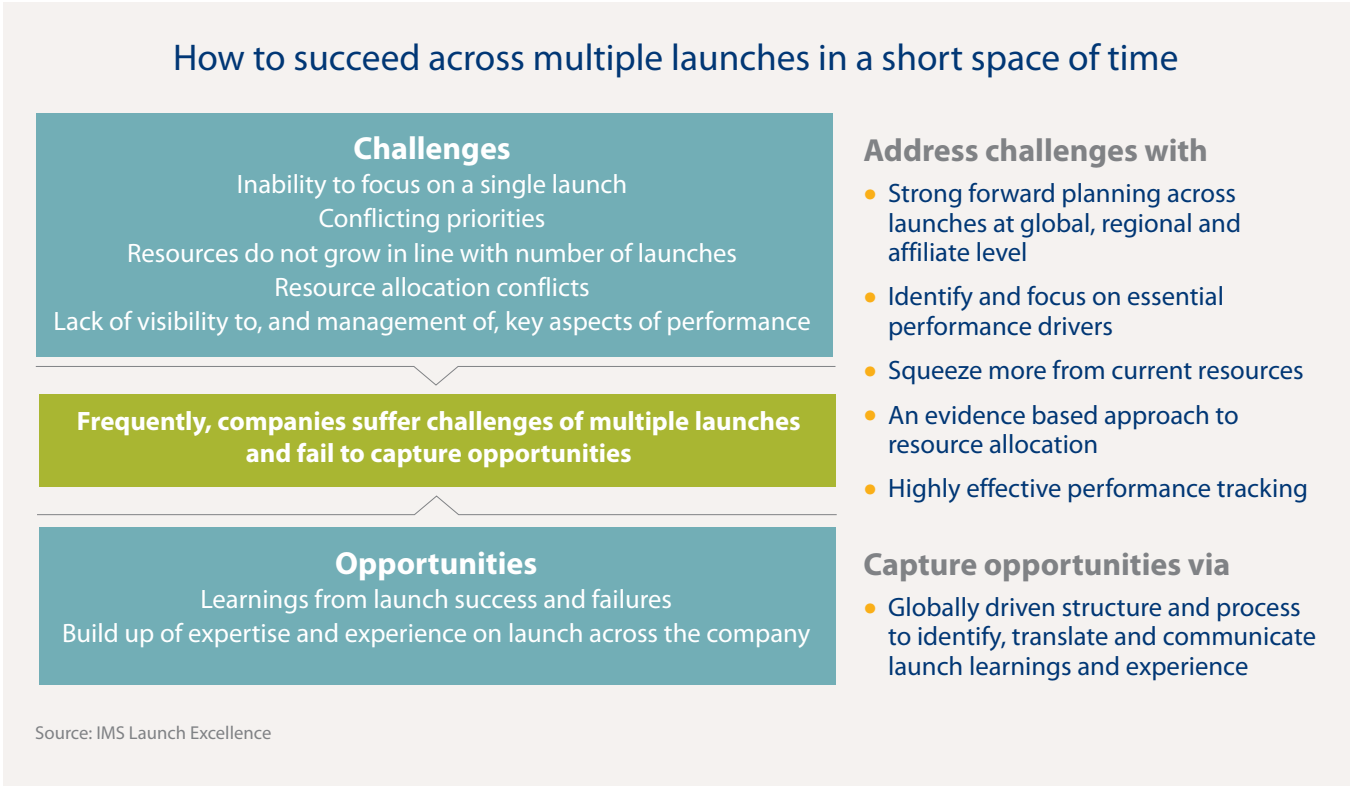
The challenge is simple: launch a larger number of products in a shorter space of time, and make a greater proportion of them excellent launches. To do this, companies must launch excellently in a greater proportion of the countries that constitute the majority of a launch's global potential. However, as our Launch Excellence studies show, companies have not, historically, been good at addressing this challenge. The choice, in fact, has historically been stark – companies can either launch many products, but have a low chance of excellence for individual launches, or launch infrequently and improve their excellence hit rate. If a company is a small to mid-sized entity, propelled by a single launch, that is not a problem, and the rise of the small to mid-sized company with a blockbuster launch is testament to that. For a major company which aims to continue to generate substantial revenues from protected innovative products, however it is very much a problem: to continue in the protected segment, companies must launch multiple products consistently excellently in a short space of time, and, historically, they haven't been able to do that.

IMS believes that some companies, recognizing this challenge, have put into place the structures and processes to address it. Others have yet to, and will suffer if they have a packed launch schedule but have failed to change their approach to launch planning and preparation.

The features of an effective approach to high intensity launch situations should minimize the negative impacts of multiple launches, and to capture their positive aspects (figure 10 overleaf). Negatives must be addressed using strong forward planning across launches at international and affiliate level and an evidence-based approach to resource allocation. This implies a case by case approach to launch prioritisation across countries – by first accepting that the core group of countries for each launch may not be exactly the same, and planning accordingly, and also by accepting that the traditional launch sequences may no longer be relevant, especially in the changing pricing environment of Europe.

Companies must seek to eliminate avoidable inconsistency in the execution of their launches, because every launch, and every country within a global launch plan, will count.

FIGURE 10: MULTIPLE LAUNCHES IN A SHORT SPACE OF TIME BRINGS NEGATIVES AND POTENTIAL POSITIVES



Source: IMS Launch Excellence

Minimising the negative aspects of a multi-launch situation is about launch preparation and planning processes, ones which:

- Work systematically from the definition of strategic objectives, through critical success factors for achieving those objectives, and the activities behind addressing each critical success factor
- Start planning earlier, at international and local level, to identify and overcome the conflicts of multi-launch situations, and to encourage planned and rational use of resources- making it less likely that waste of resources will happen
- Where necessary (it may not be if Business units or franchises are completely separate), ensure that plans are coordinated across launches early and regularly at international and at affiliate level – especially where potential conflicts have been identified
- Think about optimal commercial structure to support smaller launches: how to optimize resources, leverage work across different brands, and build a tool box that can easily be customized.
- Work effectively with existing resources, meaning teams need to be well aligned and processes defined and clear to everybody, in order to leverage across the markets and brands
- Establish knowledge sharing and knowledge transfer

An effective launch preparation and planning process should be able to:

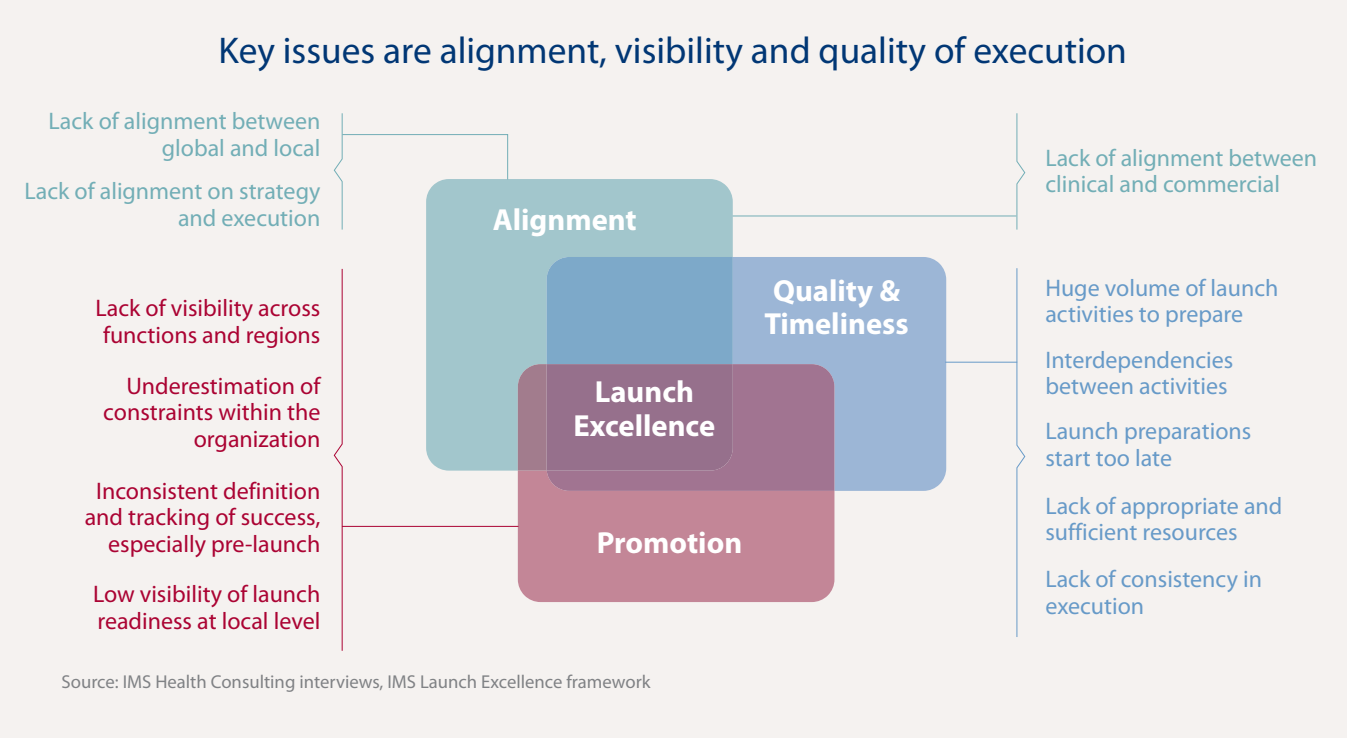
- Squeeze more from available resources- resourcing will never be able to increase in line with the number of launches occurring, so efficiency in resource use becomes not merely desirable, but essential
- Identify and focus on essential performance drivers: with multiple launches and constrained resources, focus on anything other than the essential is distracting and wastes time
- Track performance, with pre-launch preparation being of equal weight to post launch performance. In complex, multi-launch situations, clarity is essential for focus. Performance tracking should measure internal and external KPIs linked directly to execution of strategic objectives, and be comparable across launches.

High intensity launch situations also bring positives- they create launch-experienced teams and best practice learnings far more rapidly and relevantly than older, slower launch environments. It is very easy for companies to lose, or under-value these assets in the "fog of war" that accompanies a pressured launch situation. This would be a mistake. Alongside a best in class launch readiness and performance management system, companies need structures and processes to ensure:

- Best practices in launch that can be translated from one launch to another and from one country to another are identified and share in a systematic and timely fashion
- Equally, failures and mistakes in launch should be captured in an approach that encourages openness and learning
- Launch experienced individuals should be identified and nurtured and encouraged to move across launches and countries to spread their knowledge and skills.

Companies that want to succeed in the next five years in NCE launch can no longer take it on a launch by launch, country by country, basis. It will require a systematic, evidence based and comprehensive approach, from launch planning right through to performance management. Applying the Launch Excellence fundamentals, illustrated in figure 11 (overleaf), of alignment and focus behind the launch, timeliness and quality in preparation and planning, and visibility in strategy development and performance evaluation, is the start. Building a company culture of excellence and learning in launch is the next vital step to a sustainable excellence across launch after launch.

FIGURE 11: THE FOUNDATION OF LAUNCH EXCELLENCE IS FOCUS ON PREPARATION AND PLANNING



Source: IMS Health Consulting interviews, IMS Launch Excellence framework

AUTHORS:

Simone Seiter, Launch Excellence Consulting Lead, sseiter@de.imshealth.com
Sarah Rickwood, Director Thought Leadership, SRickwood@uk.imshealth.com

Methodologies used in Launch Excellence

DEFINING EXCELLENCE IN LAUNCH

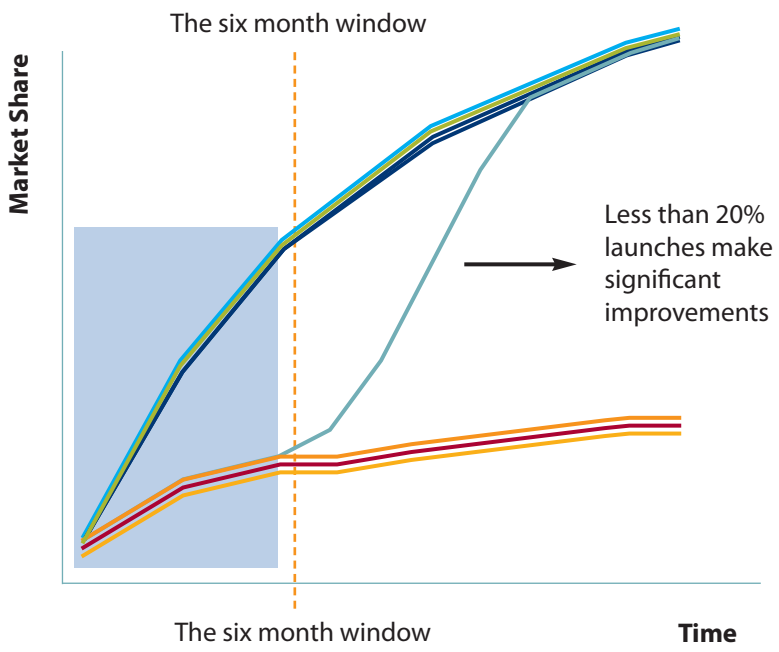
Excellence in launch can be a matter of opinion, so we wanted to base our analysis on criteria that were as objective as possible. Therefore, we devised three quantifiable measures of excellence on which we could evaluate each product.

- **Maximizing Opportunity.** Because, the vast majority of launches do not improve on the trajectory they establish in their first six months on the market, it is crucial that they achieve rapid penetration. Launch excellence, then, is characterized by steep penetration curves within the first six months, with no subsequent drop in market share for the two years post launch. We quantified this by placing all of the launch uptake curves in the country into one of ten curve groups, using a cluster analysis. Each group contained a different number of members, because they were chosen on the basis of the close similarity of the uptake curves in terms of market share achievement and shape of curve. We identified the three best curve groups and classified members of those groups as outstanding in terms of uptake curve.
- **Market-Share Leadership.** Becoming either first or second in market share within therapy class within a country within two years of launch is highly indicative of a long-term, market-leading position.
- **Promotional Out-Performance.** We established what the overall relationship, for all launches within a country, is between cumulative share of voice (promotion measured as the standard set of promotional parameters we can measure across all countries and time periods) and market share, in value terms, all defined within therapy class. On average, 90 percent of all launches within a country achieve a standard relationship between their market share and their cumulative promotional share at two years post launch. Those few that do not, whether they have a high or a low promotional share, get a better market share return than is usual for that country (i.e., the rule that 90 percent of launches follow) and are the excellent launches, promotionally speaking.

To make the cut and be considered "excellent," launches had to meet all three criteria in at least two of the eight countries we covered.

continued overleaf...

FIGURE 12: IN MATURE MARKETS, THE SIX MONTH WINDOW IS A PRECURSOR OF SUCCESS



- Analysis on non-oncological launches; we believe this dynamic will be relevant for oncologicals **WITHIN** a given indication (but longer roll-out period across lifetime of product)
- Only a **minority of launches make significant improvements** in their market share trajectory
- Whilst it is possible to improve, most do not – hence, it is extremely important to plan to **get launch right the first time**

Source: IMS Launch Excellence

UNDERSTANDING THE SIX MONTH WINDOW

The key observation of the six month window is that many launches start in an average or poor fashion in terms of launch uptake, and continue in that way. A few start very well and continue well. What is relatively rare (20% of launches or fewer) is to see a launch that starts poorly in the first six months, and then dramatically improves its launch uptake (in terms of therapy area market share in a given country) at some future point. Figure 12 in the chart above illustrates this point.

Our methodological approach to this issue is purposefully a simple one:

- It counts sales from when the product first enters the market, not when an HTA guidance is issued or a specific reimbursement level is achieved. This could be an issue for the methodology, but how it affects the result is not clear cut. IMS analysis of the impact of NICE decisions on product sales in the UK, for example, show that while negative recommendations always restrict sales, positive recommendations can have a wide range of impact on sales, from very positive to no obvious impact at all.
- Certain countries have restrictions on launches in the first six months or a year on the market – Japan and Germany are examples, and this is not taken into account. However, the new German AMNOG legislation has affected only one or two products in this study.

For Launch Excellence IV, IMS examined whether the six month window continued to influence even further out post-launch. For the 8 mature markets, it's rare for the percentage of launches that make a significant improvement versus six months on the market to exceed 20%, and even when they do it is only by a small amount; we conclude that broadly the six month rule holds.

IMS Health

EUROPE & WORLDWIDE
210 Pentonville Road
London N1 6JY
United Kingdom
Tel: +44 (0)20 3075 5888

THE AMERICAS
IMS Health
200 Campus Drive
Collegeville, PA 19426
USA
Tel: +1 610 244-200

ASIA-PACIFIC
8 Cross Street #21-01/02/03
PWC Building
Singapore 048424
Tel: 65-6227-3006

JAPAN
Toranomon Towers Office 4-1-28
Toranomon, Minato-ku
Tokyo 105-0001
Japan
Tel: 81-3-5425-9000

For all office locations, visit: www.imshealth.com/locations

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