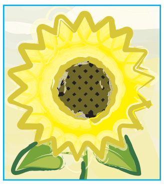

Searching for Global Launch Excellence

EXECUTIVE SUMMARY

Harsher world, new priorities

The 2009 IMS Launch Excellence™ study reflects a world that has become a very different place for doing business: tougher, riskier, and far less certain. A world in the grip of financial crisis with new complexities undermining performance and the challenges of old intensified. To better understand the impact of this change in reshaping the launch environment, we have conducted a comprehensive review into the outcomes of 1,388 products that entered the top eight markets between 2006 and 2009.

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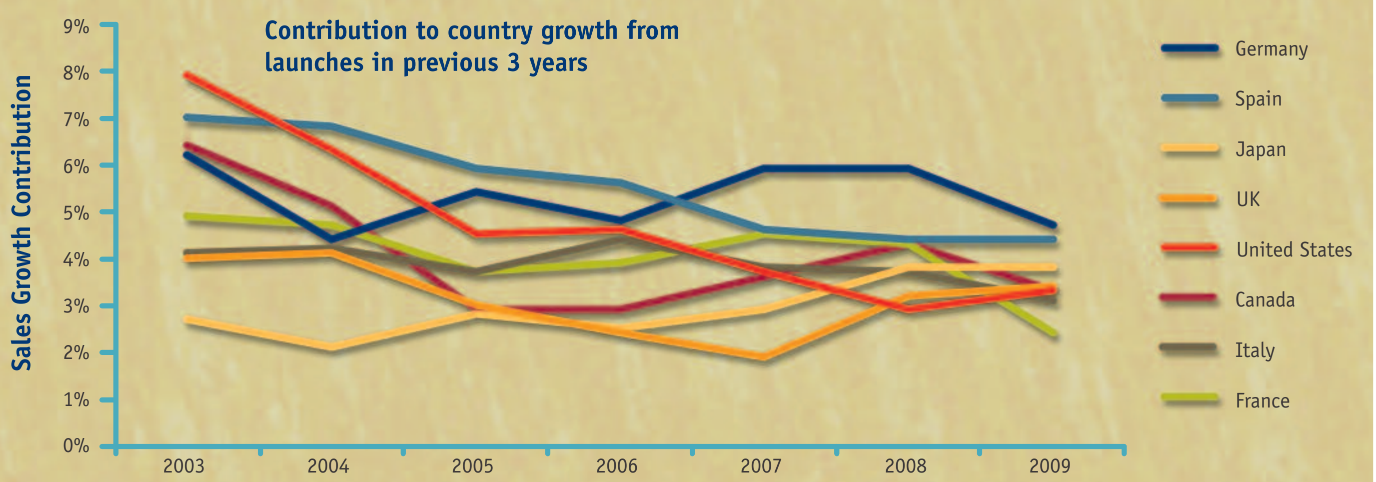
Building on the groundbreaking results of our 2007 and 2008 landmark studies on global launch excellence, this latest analysis brings a much needed update on the trends, priorities and new commercial models that are now driving launch success. The study revealed a number of key findings:

DECLINING PERCENTAGE OF EXCELLENT LAUNCHES: Only eight promoted brands (0.6%) among the universe of products we studied met our criteria for excellence in launch, down from 21 (0.7%) in our 2008 study and 35 (0.8%) in our 2007 analysis.

GROWTH CONTRIBUTION REMAINS POOR: The pharmaceutical business has long been struggling with a systematic decline in the ability of newly launched products to replace the loss of value growth when leading brands move off patent, as well as fewer launches which drive value growth by genuinely creating or expanding

FIGURE 1: GROWTH CONTRIBUTION FROM NEWLY LAUNCHED PRODUCTS HAS CONTINUED TO DECLINE ACROSS THE TOP EIGHT COUNTRIES



Source: IMS Health Consulting, Dec 2009. Total market defined as ethical brands only. Chart shows growth contribution from products <=3 years old in period vs the same products in the previous period.

markets. Our latest research confirms that launches are still performing poorly in terms of their contribution to value market growth (Figure 1).

PROGRESSIVELY LOWER MARKET SHARE: In comparing our two previous launch excellence studies, we found that even the minority of launches that achieve 5% or greater value market share in their first year are obtaining progressively lower market shares in seven out of the eight countries studied.

In six out of the eight countries there has also been a significant decline (averaging 15% across these six countries), in the market shares achieved by the very best launches per country, and some decline in all but one.

One of the underlying drivers, but not the sole cause of these declines, has been the dearth of innovative new launches entering the market. However, there are signs that this trend may be reversing. After reaching a likely low point in 2008, when the anti-thrombotic Xarelto® (rivaroxaban) was the only launch singled out by most analyst opinion as a prospective blockbuster ($1bn in global sales), the pipeline for launches with major potential is showing signs of revival: a raft of important upcoming entrants, primary care and specialist, promises to create new markets or revitalize existing ones (Figure 2).

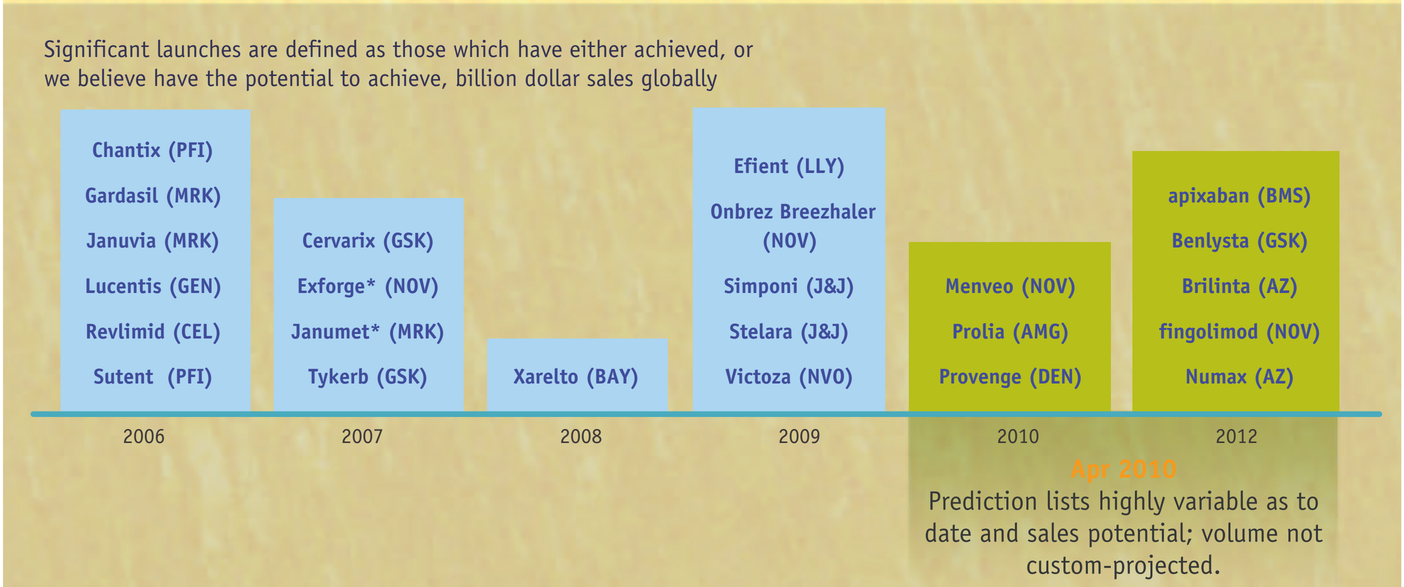
REDUCED POTENTIAL: Recent major launches include products which, had they entered the market at the outset of our launch excellence analyses in 1997, undoubtedly would have become blockbusters.

Today, with greater genericization across many key therapy areas and more powerful payers who have the means and motivation to control the uptake of new products, launches often have more modest potential.

New launches into therapy areas where effective treatments are generic and inexpensive can struggle to avoid relegation to the smaller pool of second-line patients for whom first-line generic agents have failed.

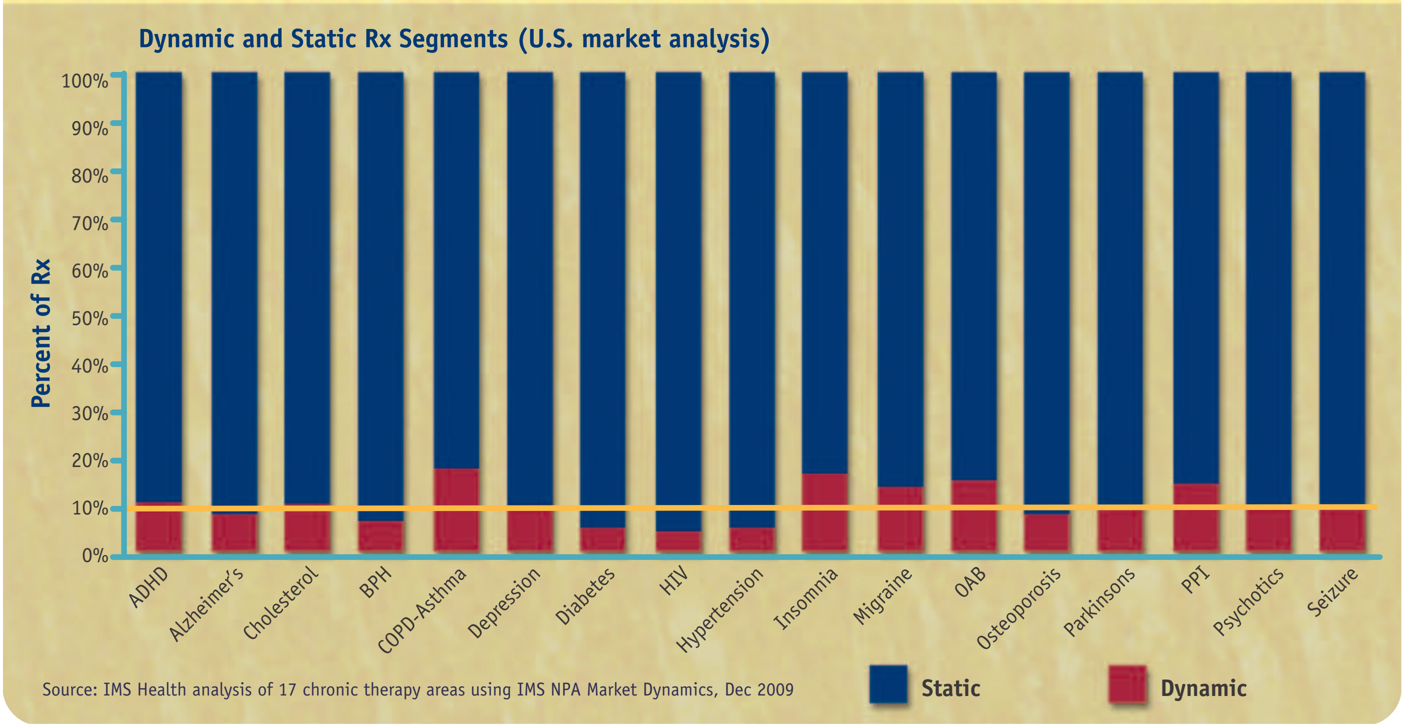
With the largest-ever collection of lost exclusivities due in 2011, when some $42bn of product sales will lose patent protection across the eight markets of our study, this trend toward reduced potential will be exacerbated for all but the most differentiated of new launches.

FIGURE 2: THERE ARE SIGNS THAT THE NUMBER OF MAJOR PRODUCT LAUNCHES MAY RISE FROM A 2008 LOW POINT



Source: IMS Health, Market Insights, Apr 2010. *Combination product

FIGURE 3: ON AVERAGE, THE DYNAMIC MARKET REPRESENTS ONLY ABOUT 10% OF THE TOTAL MARKET



Source: IMS Health analysis of 17 chronic therapy areas using IMS NPA Market Dynamics, Dec 2009

FIRST SIX MONTHS STILL CRITICAL: A key learning from our previous two studies was that the vast majority of launches have only a short window of six months to make their mark. Those that do well in that timeframe continue to do so and vice versa. Rarely do those that start poorly dramatically improve after six months. Our latest study shows this is still the case: fewer than 20% of launches significantly improve their uptake trajectory between six and 18 months on the market.

SMALL AVAILABLE MARKET FOR LAUNCH PRODUCTS: In our 2008 launch excellence study, we noted that within the six-month window there lurked an even shorter critical time frame; on average, three months is the period in which a launch agent establishes its share of the dynamic market in its therapy area.

The dynamic market is the ultimate key to launch success and for a very simple reason – the initial launch trajectory of a new product is created by the drug being prescribed for new patients, by having existing patients switched to it or by being added on to their existing regimens. In established markets for chronic conditions, the share of the market that consists of new, switch or add prescriptions can be surprisingly small.

An IMS study of 17 major chronic therapy areas in the U.S. found that in all cases the proportion of the market that was "dynamic" (that is, consisted of new, switch or add prescriptions) was on average a mere 10% of all prescriptions (Figure 3). The remainder of the market comprises static or repeat prescriptions, the patients who are least available for a new launch to gain.

FURTHER LOSS OF PRESCRIBER DECISION-MAKING POWER: In this third study, as in the previous two IMS Launch Excellence studies, we have observed an ongoing decline in the impact and predictability of the relationship between prescriber-focused promotional investment and launch market share achievement, in the early years of launch.

The overall trend is toward a loosening of the relationship between prescriber-focused promotion alone and market share achievement, as other investments and factors become increasingly important in determining which launches succeed. This reflects the weakening decision-making power of the individual prescriber as the key or dominant decision maker on whether a launch gains widespread use.

In the U.K., in primary care, there is no longer any predictable relationship, however weak, between the investment in clinician detailing alone and the market share achieved by the launch. This is a significant change from our previous two studies, where there was still a robust statistical relationship between the degree to which share of detail alone explained therapy market share in the U.K. However, the results from this study are consistent with the trend observed across the previous studies, with share of detail explaining 16% of launch behaviors in the first study, and only 2% in the second.

THE NEW LAUNCH EXCELLENCE MODEL

Companies are acknowledging, but not yet consistently responding to, the new demands of the changing launch environment. For those in search of a successful launch, there are still opportunities to excel but these will be contingent on a shift in mindset toward a new and very different model.

Our research has identified three recurring themes that are common to every excellent launch and which we believe will be the key to launch success in the future.

These are:

1. **AN ALIGNED AND PREPARED ORGANIZATION**
2. **A POWERFUL AND PERTINENT VALUE PROPOSITION**
3. **EFFECTIVE AND EFFICIENT STAKEHOLDER ENGAGEMENT**

Companies that focus on these three core success factors will be positioned to maximize the five drivers of uptake that critically build market share:

1. **ACHIEVING BRAND ADVOCACY** among regulators, payers, key opinion leaders (KOLs) prescribers, patients and other stakeholders, with an early focus on creating the right value proposition
2. **GAINING BRAND APPROVAL** at a regulatory level with optimal positioning and labelling for the right patients to maximize brand success
3. **SECURING MARKET ACCESS** on the right terms with national and local payers
4. **ATTAINING BRAND ADOPTION** for the optimal patient segments with a focus on working with prescribers and providers to achieve early strong positioning in the dynamic market (new, switch, and, if relevant, add-on patients)
5. **ENSURING BRAND ADHERENCE** by retaining patients as loyal repeaters for as long as is clinically appropriate.

FOR MORE INFORMATION

For more information about IMS expertise in Launch Excellence, please visit www.imshealth.com/launchexcellence

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