Launch perspectives: The new rules for success in pharmaceuticals

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There has never been a more challenging time for product launch in the pharmaceutical industry.

Approvals are at an all-time high, the market is more competitive than ever, and there is an urgent need to refresh revenues as a wave of products go off-patent. Centralised reimbursement and formulary decisions mean success at the point of launch is binary. The future looks tough. And the industry's recent track record with product launches is poor: two thirds of pharma launches between 2003 and 2009 performed below forecast[1]. In addition, sales are down (with peak sales 30% down on 1996 levels) and 90% of launches in Europe face restrictions from government or payers[2].

This means a dramatic rewriting of the rules for a successful product launch. How can pharma companies learn from their past and from other industries to respond to the new rules for success?

New products, new markets

Pipeline analysis carried out by Bain & Company reveals that the product portfolio mix of a typical pharma company has changed in recent years. Whilst in the past, companies used to launch a few, large products a year, they are now launching many smaller products – which are exposed to more intense competition[3]. The success of these launches represents an important new source of revenues, to offset patent expiries. Now is an exciting and challenging time for pharma launches, with a large number of product launches due – albeit at lower value than historical averages.

52% of doctors
in the UK say they don't see reps in a typical week

12% reduction
in sales reps in EU, 5% in 2013 alone

Not only are the number of launches at an all-time high, but the marketplace itself is changing. Recent years have seen a shift in the buying behaviour of physicians, who

[1] EvaluatePharma: McKinsey & Company Analysis
[2] "A new pharma launch paradigm", Bain & Company
[3] "A new pharma launch paradigm", Bain & Company

are more reluctant to meet with sales representatives and who are attending fewer conferences. The criteria for a successful pharma launch have changed: everything from value proposition and price; to patient segmentation evidence requirements, engagement and sales channels; have become more complicated. Despite efforts to add new digital channels to connect with physicians, with an increase in digital spend of 40% in the EU 5 from 2011 to 2013, overall spend has remained flat. Furthermore, 42% of physicians in the UK say they have never visited a company website.

Launch is hard

McKinsey & Company report that 66% of pharma product launches between 2003 and 2009 performed below forecast[4]. However, pharma is not the only industry facing increasing launch challenges. Consumer product launches experience many hurdles also common to pharma.

A 2014 global study by Simon Kucher & Partners revealed that, across all major industries, 72% of all product launches fail to meet their revenue targets[5]. Why do so many consumer product launches fail? Schneider Associates, a Boston-based launch PR and marketing agency, reports that too often a focus on designing and manufacturing a product can see players unprepared for its launch. Products which do not fully match customer needs, or unforeseen moves by competitors can also lead to failure. Above all, with every launch it becomes even more difficult to break through the 'noise' generated by the crowded marketplace of existing products and extensions[6]. Sound familiar?

Joan Schneider and Julie Hall, co-authors of "The New Launch Plan" report that, in the USA, less than 3% of consumer packaged goods exceed sales of $50m in their first year - considered the benchmark of a successful launch. Building on insight drawn from a Harvard Business Review analysis of consumer product launches, five common mistakes can be identified from which the pharma industry can learn[7].

[4] EvaluatePharma: McKinsey & Company Analysis
[5] "Global Pricing Study 2014", Simon Kucher & Partners
[6] "Why most product launches fail", Harvard Business Review
[7] "Why most product launches fail", Harvard Business Review

Five common launch mistakes

1. The product is revolutionary, but there is no market demand

Google glass: futuristic, wearable technology glasses were introduced to the market in 2013. However privacy concerns, a hefty price tag and a market who failed grasp the 'point' of the product, alongside the perception of the glasses as 'uncool', led to their removal from the market in January 2015[8]. *Lesson: knowing who is going to buy your product, and at what price, is crucial.*

2. The product is confusing to customers

Scentstories, an air freshener in the shape of a CD player employed a celebrity spokesperson for its launch – the product and its campaign were confusing to customers, and the launch failed. The product occupied a new category, but did not receive the necessary customer education required to support its introduction[9]. *Lesson: revolutionary products need a strong educational campaign.*

3. A product which does not have distinct enough benefits

Launched in 1992, Crystal Pepsi was a clear and caffeine free drink promoted as a healthy, diet beverage. Despite strong first-year sales, customers were not convinced by the health angle – although colour and caffeine had been removed from the drink, to most, Crystal Pepsi did not present an image of a healthier soft drink. The product was not distinctive enough, existing in 'product limbo'. By the end of 1993, Pepsi Co. had pulled the product from the market[10]. *Lesson: make your product distinctive enough to sway buyers.*

4. A product which fails to meet expectations

What has come to be known as the 'Titanic of Automobiles', the Ford Edsel was launched to much hype in 1957, but failed to live up to high expectations, with only 64,000 being sold in the first year. Despite the $400m investment by Ford, the word 'Edsel' has become a popular symbol for failure[11]. *Lesson: Do not release a product to market until it is truly ready and has been thoroughly tested.*

5. Being unable to keep up with the pace of growth

The Mosquito Magnet, launched in 2000, quickly became a top-selling product.

[8] "Has Google Glass failed?, The Daily Telegraph
[9] "Why most product launches fail", Harvard Business Review
[10] "The 10 worst product fails of all time", Time Magazine
[11] "Why this historic Ford flop is one of Bill Gates' favourite case studies", Business Insider

However, when production was expanded to a mass-production plant in China, quality dropped, consumers became angry and the product was taken off the market. American Biophysics, the company producing Mosquito Magnets, once having annual revenue of $70m, was sold for $6m[12]. *Lesson: Having a plan in place to be able to scale rapidly if a product takes off is essential to protect brand and product reputation.*

Pharma struggles

Building on the lessons drawn from consumer product launches, why do pharma launches fail? Fierce Pharma, the popular blog, identifies the major reasons as insufficient launch resources, high prices, risk concerns and failure to understand the market[13]. Their research lists a set of launches they believe have struggled and why.

Human Genome Sciences' launch of Benlysta for lupus, Savient's launch of Kryotexxa for gout and Somaxon's launch of Silenor for insomnia all struggled to achieve the success desired as a result of insufficient resources being dedicated to the launch. Other launches have struggled due to an incomplete understanding of the market or competitive environment. KV Pharmaceuticals launch of Makeva, for preventing premature birth, experienced challenges as they did not fully understand the competitive environment. Xeonoport's Horizant for restless leg syndrome saw little market demand and was also subject to FDA delays. AstraZeneca's Brilique anti-coagulant too experienced FDA delays, which, combined with regional payer resistance, created difficulties.

Dendreon's launch of Provenge for prostate cancer struggled due to a combination of regulator misunderstanding, the market not being ready, and a price which was too high. Sanofi's Zaltrap for colorectal cancer also saw an adverse public effect to pricing. Being priced too high, and experiencing an unexpected insurer response created challenges for the launch of Rare Disease Therapies' Anascorp for scorpion bites, and insufficiently addressing concerns on risk meant difficulties were encountered during the launch of Sanofi's Multaq for heart disease[14].

[12] "Why most product launches fail", Harvard Business Review
[13] "10 top drug launch disasters", FiercePharma
[14] "10 top drug launch disasters", FiercePharma

Reflecting on these struggles, the significance of dedicating sufficient launch resources, on both marketing and education of the product is clear. Apparent also is the need to have a deep understanding of the market, and its unmet demands. This, alongside a fully considered pricing strategy, will help create a product that is truly appealing and relevant to the market it is being launched into. There would be few marketeers in the industry that could not list these as priorities, so we need to consider why do we fail to do some of the core basics of marketing well?

Success stories

There is also good news, with 26% of pharma product launches outperforming their forecast[15]. Thorough education, improvements in drug administration and lower prices have all contributed to what Fierce Pharma consider to be 'pharma's biggest successes'.

Biogen's Tecfidera for MS, which made an 'innovative response' to reimbursement delays, used a marginally lower price than Gilenya, and solid data around tolerability. Novo Nordisk's launch of Victoza for diabetes performed well on the back of major head-to-head studies, growth of their US salesforce, and making the most of the company's position in diabetes.

The launch of Bayer & Regenon's Eylea for macular degeneration is viewed as successful due to a better dosing regimen, with a small price difference per injection which became significant per annum. Bayer and Johnson & Johnson's launch of Xarelto went to plan as Pradaxa (BI) took the burden of educating the market and lawsuits of early bleed worries. They also got acute coronary syndrome approval first, with the right data for the EU.

Gilead's Stribild for HIV gained strong key opinion leader position, with their product being at the core of treatment… although the high price may come back to bite them. Johnson & Johnson's Zytiga for prostate cancer had the benefit of being orally administrated (Provenage is injected), with significant median survival improvement data, but this drug faces major competition. BMS's Yervoy for melanoma has been

[15] EvaluatePharma: McKinsey & Company analysis

the first new treatment option for some time to drive growth, but there is pressure on price, and real-world evidence is being reviewed[16].

Gaining market acceptance and approval, with a product which has distinct benefits and an appropriate educational campaign has been core to these pharma successes. Each launch has succeeded by excelling in at least one element of the proposition – offering to the market a benefit distinctive enough to sway buyers and achieve success. This is not rocket science, but we often struggle within this industry to get this right. So what can we learn from the real rocket scientists?

Rocket science

Taking a step back from the world of commercial launches altogether, let us consider the launch tactics of arguably the most challenged and successful launchers of all: NASA. Since its creation in 1958, NASA has become a leading force in scientific research and discovery, with 2014 alone seeing ten successful NASA launches to the International Space Station.[17] However, despite its success, NASA is not immune to failure – the space shuttle programme had a flight failure rate of 1.5%[18]. That's a big issue for multi-billion dollar manned flight.

The fuel for success...

- Skills & experience
- Risk management
- Ongoing management
- Resources

So what do they focus on?

Pre-launch, training is extensive, with highly skilled teams of experts, including former astronauts bringing a wealth of **launch skills and experience**. NASA has a rigorous approach to **risk management** before, during and after launch: they have embedded processes, run multiple scenarios and have whole teams focussed on risks of failure. Post-launch, there will be **constant and ongoing monitoring of multiple data sets**, with regular cross-functional team reviews. NASA dedicates a huge wealth of **resources** to launch – with a budget of eighteen billion dollars for the fiscal year 2015[19].

[16] "10 top drug launch disasters", FiercePharma
[17] NASA missions calendar, NASA website
[18] "5 Horrifying facts you didn't know about the space shuttle", Forbes
[19] Fiscal year 2015 budget estimates

In pharma, launch skills and experience tend to be much more limited. Often, pre-launch training will take the form of a two day workshop, nothing more. Approach to risk is also radically different; typically managed adhoc, monitored as part of strategy, but not often revisited. Post-launch, rather than constant monitoring, a pharma company will usually gather weekly core launch data, with interval reporting to teams and senior management. Resources are also often tight, employed close to launch.

Launch 101 - why don't we do it?

The large consulting firms all suggest that well delivered marketing is the key to a successful launch. There must be a thorough understanding of the market, its influencers and their needs. The value proposition must be compelling, the approach multichannel, and tools should be in place to monitor the launch. Companies must ensure that resources and plans are in place to **ensure** that the essentials are being done.

This does not tell us anything we do not know, the real challenge is moving away from a 'ticking boxes' mind-set to one in which we deliver elements of the proposition to an outstanding standard - excellence is key.

The new rules for success

Looking to the future, executing the basics well will not be enough for launch success. The rules for a successful launch are changing too much, too fast. Recent years have seen a constant rise in expectations: what used to be acceptable is no longer sufficient. It is essential to go beyond the core launch activities, setting the standard for future innovation and success. Pharma has seen significant shifts in six key areas: value proposition, price, patient segments, evidence, engagement and channels, which have all become more complicated.

	From...		*To...*
Value proposition	Single value proposition	→	Multiple for different payer and physician types
Price	Defined by physician research and negotiations	→	Defined by value assessment, tenders etc.
Patient segments	Go broad	→	Go for where you can secure a strong position for growth
Evidence	Clinical, limited national HEOR	→	Clinical, national & regional HEOR, real world evidence
Engagement	KOL's, physicians, limited payer/ policy maker 12-18 months before launch	→	National & regional payers, hyper influence physicians, 'other' influencers from 3 years pre-launch
Channels	'Traditional sales channels'	→	Multichannel, with significant differentiation by customer value

A launch innovation checklist

So, it is no longer enough to perform the basics well – but how can we achieve success? Constant innovation is required to remain one step ahead of the competition. Beyond 'launch 101', several key innovation areas can be identified…

1. **Early and ongoing external engagement.** This could be through 'medical' engagement, early player engagement (more than three years out) or a living value dossier.

2. **Sufficient resources** must be allocated. For example, by front loading investment and having mechanisms in place to adjust.

3. **Flexible resourcing** is a valuable tool, for example by making sure there is marketing support for the initial launch within the sales force: ensuring that there are sales representatives who can work across therapeutic areas, contract sales and co-promote.

4. **Highly skilled launch teams.** This could be achieved by setting up a launch academy, to provide in-depth, dedicated training prior to launch, or by having a dedicated launch factory – a team who are solely responsible for product launches, specialised in launch tactics, rather than re-training a new team for each product launch. Launch factories are commonplace in technology companies such as Microsoft and Apple.

5. **Adaptive launch management,** through launch wargaming and modelling of various potential scenarios, can allow launches to be managed as reactively as possible. A dedicated launch tracking team, following the progress of a launch, with well thought-out solutions to various scenarios means a launch can be managed as dynamically as possible. With detailed contingency plans, and resources to make changes, launches can be managed as successfully as possible.

6. **Deep real world analytics**, with dedicated analytics teams combining all data sources to give a thorough understanding of launch success – with real-time information being tracked and reviewed. Procter and Gamble use launch and performance data rooms to track their launches live, with over 50,000 personal "cockpits" allowing individuals within the firm to access real-time updates and daily reports.

Excelling in any of these offers a potential path to success.

Adapting to change

The past decade has seen major changes for all industries, and the future looks set to provide even more challenges. The rules for pharma launch success have changed. It is essential to review how the rules have changed, and whether upcoming launches have been adapted accordingly: Launch 101 is no longer enough, innovation and excellence are essential for future success.

A key first step in preparing ourselves for the future is through the identification of our own in-house launch gurus: team members who are trained to become experts in launch strategy. By drawing on lessons from pharma and other industries, we enable them to lead the successful launches of the future.

Turning to your own business, it is critical to consider following key questions, as the answers will form the foundation for future launch success…

1. How are we making sure we are doing 'launch 101' to an outstanding level, not just ticking boxes?
2. What breadth and depth of pharma launch experience do we have in our organisation today?
3. Are we developing capabilities in the innovation checklist, at scale?
4. What will be the key innovations for success relevant to our launches, business and organisation?
5. Do our cross functional teams have a shared view of how the rules for success have changed?
6. In what aspects of launch are we going to outperform our competition?

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