41 Drug Approvals in 2014 – good news for the industry or the start of more challenging times?

‘Biopharma posts a chart-topping 41 new drug approvals in 2014’ was the headline on the 2nd January 2015 from www.fiercebiotech.com. The article goes on to explain that ‘A burst of new drug approvals at the FDA just before Christmas pushed the total to 41 for 2014, the fastest pace in the past 18 years’1. The situation is similar for drug approvals through the EMA, these have also increased steadily over the last 3 years. Some companies were better positioned than others to benefit from the number of new drug approvals, many of the winners were ‘dominant biotechs with carefully focused pipelines’ who delivered ‘major new approvals with significantly less spent on R&D’1 such as Gilead, Celgene and Biogen Idec.

So what does this mean for the industry? What opportunities are there within this trend of increasing new approvals and where should our concerns lie? With this apparent approval success will need to come the humility of making each brand a core part of the treatment armamentarium. This paper outlines 3 points for consideration and looks at the impact for future launch team planning.

1. Pricing Strategy – the evolution to an ‘Access Enabled’ Strategy
2. Differentiation will really need to be different
3. Defining the right patient for the right result

1. **Pricing Strategy needs to evolve to an ‘Access Enabled’ strategy**

Regulatory approval no longer means unrestricted access for the new medicine to be prescribed, regardless of how many new drugs the regulators approve. The publicity surrounding the increased approvals from the FDA & EMA will be making many a budget holder nervous as they reflect on how cost implications and the restrictions that may be required. Some of the more successful new entrants in 2014 stole a march on their competitors by developing a stronger pricing and value based offering. A good example of this is AbbVie with Viekira Pak for Hepatitis C. The dosing regimen from AbbVie is less convenient than the options from competitor company Gilead, however AbbVie took the time to better understand the needs of the payers and their feelings towards Gilead and the perceived high prices. The resulting discount pricing model has enabled AbbVie to gain exclusive positioning on key formularies¹.

Did AbbVie do a better job at considering the external environment and the perceptions of key customers groups about different companies? Did AbbVie utilise the full Marketing Mix to assess and more appropriately define product positioning, price and ultimately patient needs? The regimen may be less convenient for patients than the Gilead option, but will still be more convenient than not being able to access the treatment at all.

2. **Differentiation will really need to be different - and adaptable**

So what does this mean? It means that in many therapeutic areas a growing price competition is unfolding. The larger companies have invested in these areas over many years but patent expiries are enabling smaller companies to enter these markets and launch generics or branded generics with a lower price ticket. The threat for ‘Big Pharma’ is that these newer entrants are not interested in outright market domination but are focused on gaining share in accounts which meet certain criteria, accounts which, for a number of reasons, are more fertile for considering different treatment options. Consequently the newer entrant companies can more specifically support the needs of these localities and build their market presence in a way that ‘Big Pharma’ with heritage and full disease

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¹ 41% of the product sales reported by Big Pharma in 2013 are no longer protected by patents⁴.
area coverage seems unable. The learning we can from this is that all of those companies wanting to achieve ongoing success in key therapeutic areas will need to keep very close to their customer groups to continually reflect and assess their changing needs and the benefit they perceive from the treatment in question. What was a strong differentiator at launch and in the early years may not be enough to ensure continued success at maturity. Equally the expectations, perceptions and beliefs of customers will also evolve from early launch years to maturity – they have taken part in the journey but may not have arrived at the same destination.

3. Defining the ‘right’ patient for the ‘right’ result

The third and most important aspect of the increase in treatment approvals is the impact on patient expectations. Many of the recent and upcoming approvals are for rare diseases and cancers which lead to greater media interest. This has the result of turning the front-line treating Healthcare Professional (HCP) into a naysayer and gatekeeper as they grapple with identifying the appropriate patient for the new treatment. One of the most sorely neglected aspects of new treatment launches is the support provided to the HCP team to help them identify the most appropriate patients and then communicate effectively with each patient to help them understand the treatment in question. It is often only a couple of years post launch that the theme of how to clearly and quantifiably identify an appropriate patient is explored by the drug company which is often too late to influence the initial HCP and patient experiences. Understanding the dialogue between HCP and patient is an underutilised way of gaining greater insight into unmet needs.

Impact on launch planning and delivering launch excellence

What impact does the increase of approvals have for future launches?

- **Excellence in launch planning is set to become even more important than ever.** Increasing noise in the marketplace, cost constraints and pressures and ever more complex treatments mean that the development and execution of an excellent launch plan could be the difference between success and failure. No longer can we rely on ‘the company standard launch
process’ to be enough to achieve our visions for brands – the off-the-peg approach will need to become bespoke.

- **Better understanding of how to help the budget holders enable access may achieve greater access impact.** Do you understand what treatments have previously gained access with your payer customers and, more importantly, why? Have you taken a more holistic view on understanding how your payers could agree to enable access rather than just agree (or disagree) with a straightforward price? Broadening the analysis as part of the launch plan may provide different and more competitive insight to be leveraged.

- **Clarity of communication at all points in the journey of the brand will become increasingly important.** It is no longer enough to develop a key message resource from which all communications are pulled. We need to look beyond ‘what’ is being said but also ‘how’ we are saying it. Market leadership arrogance will be punished because flexibility, practical support and ‘a better overall fit’ can be achieved elsewhere.

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