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Are You Prepared for the Biologics Patent Cliff?

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ADVANSTAR

Biologics: The Next Patent Cliff

How can biologics brands prepare for their own imminent patent cliff? Paul Gardiner and Dr Clifford Hall propose some late life cycle options.

Since the arrival of the first biosimilar products in the market we have seen that the impact on the originator brand is not the same as with the introduction of a traditional generic. While the generic patent cliffs are drying up, biological brands with a global market value of over 40 billion US dollars in annual sales are expected to start losing patent protection by 2016. The list of brands facing this challenge includes several well-known blockbusters in oncology and autoimmune diseases. However, the impact of this next wave of biosimilars will depend to a large extent on the readiness of big pharmaceutical firms to counter this threat. We propose an actionable framework to address this new challenge.

Assessing the landscape

Human insulin and interferon are two relevant analogues of biosimilars that were late stage development casualties that did not pass regulatory review in Europe. There are many other examples of patent-expired biologicals where no biosimilar has been marketed. There are several factors influencing the likelihood of biosimilar market entry. These include development costs, complexity and risk, the overall size of the market, and whether there is a risk of new treatments making older treatments obsolete.

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By the time that a biosimilar reaches Phase 2/3 development it is time for originator brands to consider biosimilar market entry as a credible threat, to analyse the situation and implement late life cycle plans accordingly. Once the potential future competitor has reached this stage, the probability of technical and regulatory success has gone up substantially yet there is still no guarantee of commercial success.

The peak penetration of biosimilars over four years has been between 10 and 35%. However, the experience in Europe with the approvals of somatotropin and filgrastim provides contrasting examples. Biosimilar somatotropin's share of the market was consistently below a 10% unit share across the major EU markets in the three years following launch. This was in sharp contrast to the more than 50% share achieved by biosimilar filgrastim in France, Germany and the UK and shares of over 20% in Italy and Spain. This variable uptake across the major European markets reflects the relative influence of local pricing and reimbursement policies and stakeholder influence and attitudes to the adoption and use of biosimilars. The level of "readiness" of a market for biosimilar introduction is thus also a factor in determining which countries see the first launches of biosimilar competitors.

The price erosion of the originator brand following biosimilar introduction has been modest and in the range of 20 to 40% in Europe. This is a reflection of the level of competition with only two somatotropins, four epoeitins and seven filgrastims in Europe. There is also a tendency to price close to the originator and then to compete for share using institutional rebates and contracting rather than competing directly on price.

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We have analysed and modelled the multiple factors influencing the biosimilar market share. Table 1

Table 1: Factors that allow the identification of the severity of biosimilar exposure, and development of measures to address the threat.

Category	Influencing Factors	Impact on Uptake	
Biosimilar product characteristics	• Dose, administration and storage • Device compatibility • Indication statement	Lower convenience e.g. storage and administration	↓
		Identical indication statement	↑
Disease state	• Chronic vs. Acute disease • Drug treatment effect • Speed of clinical effect	Rapidly observable clinical effect	↑
		Reluctance to switch therapy in chronic disease	↓
Physician	• Efficacy, safety & immunogenicity perception of biosimilars • Willingness to switch therapies • INN and product names	Positive previous experience with biosimilars	↑
		Data supporting interchangeability of products	↑
		Lack of data or expert consensus on the issues	↓
		Originator and biosimilar have different INNs	↓
Patients	• Patient choice & convenience	Ease of use e.g. device design	↑
		Inconvenient dosing schedule	↓
Payers	• Budget constraints • Pricing & Reimbursement	Strong budget pressures	↑
		Drug utilisation controls	↓
Substitution	• Legal & regulatory status	Automatic substitution	↑
		Non substitutable lists	↓

summarizes some examples of factors that are inputs into our tool that allows companies to identify the severity of their biosimilar exposure, and to develop measures to address the threat.

The insights gained from an understanding of the likely price and volume impact on your brand from the above drivers and barriers are key to formulating and implementing a strategy to defend your brand.

From planning to action

Our approach is to take the key lessons learnt from analogues, including past biosimilar launches, in terms of uptake and experiences across key stakeholder groups. These may include not only health care providers and patients but also regulators, policymakers and those responsible for contracting and pricing at the payer level.

From this approach it has become clear that it is critical to define how to maintain brand loyalty and differentiation in the minds of patients, health care providers and payers. Communications and programmes that are up and running a year or more in advance of the expected launch date stand the best chance of achieving their goal.

Below are some examples of

programmes that have been successful in contributing to the achievement of overall brand objectives.

• **Mapping the landscape.** Map the andscape both internally and externally, identifying the key people and functions, the roles they could play and their influence on key decisions, in order to ensure cross functional internal coordination and a well considered approach to the external players.

• **Providing services beyond the product.** These programmes directed at providers and patients to add value, differentiate and build brand loyalty.

• **Entering into innovative contracts.** Engaging local payer customers in innovative contracts can provide a basis for improved outcomes, more real world data including recent cost-effectiveness information, in addition to managing the financial risk to the local payer.

• **Initiating medical programs.** Attention should be paid to continuing investment in answering relevant medical questions using disease or patient registries as well as health outcomes research approaches.

• **Engaging your industry association.** While many of the activities are going to be specific to the brand team or to other functions in your organization, the analysis may reveal issues that are broader and not brand or company specific. These may relate to the industry as a whole or to a specific disease state or therapeutic class. In these situations it is more appropriate to engage your relevant industry body in the issue and debate.

• **Develop a position paper.** Given the range of internal departments that can be involved in implementing your strategy as well as the potential involvement of your industry association, you should ensure that you develop a position paper within the company that makes sure that positions are clear, structured and substantiated.

It is useful to prioritize these potential programmes based on the scale and strength of the threat posed by the new competitor. A watching brief for new developments would be sufficient in the face of a low probability of the competitor being approved and a low expected commercial impact. A selective approach is appropriate in many circumstances but you may want to pull out all the stops if there is a high likelihood of a strong, high impact competitor that could eat your lunch.

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At a time when many pharmaceutical companies start to pull back on anything other than short-term investment in a brand, there is an interesting case here to maintain that investment support for longer and for a targeted investment in a defence strategy. For a 1-billion dollar product, every 10% share that is not lost to a competitor could be worth around 400 million dollars over five years.

Conclusion

While there is uncertainty about the probability and impact of biosimilar competition there are insights that enable one to assess, quantify and plan for the risks. Post-patent sales erosion is very unlikely to be as steep as the post patent cliff seen with generic competition. This creates an opportunity for the originator brand to compete and coexist with biosimilar compounds, and a market dynamic more akin to that seen with branded, on-patent pharmaceuticals in a crowded therapeutic area.

There is a strong business case for the necessary investment to defend your brand. Timely investment in developing and implementing a robust strategy can pay dividends with a significant contribution to company top-line sales performance for years to come.

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