CEPTON
Strategies

Biosimilars: the Market is Taking Off

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A slow, uncertain start

The market of biologics (ca $ 200b in 2015[1]) accounts for 20% of the total drug market and is by far the most dynamic and profitable segment (7% growth vs 3% for the total drug market).

However, although some biologics have already lost patent exclusivity for several years, "biosimilars" have been growing very slowly, as opposed to generics. The US stayed away for many years, in emerging countries where biologics have hardly penetrated for cost reasons, biosimilars have become dominant, but markets are very small. Europe appears to be the only significant market today, but figures are still modest. Why?

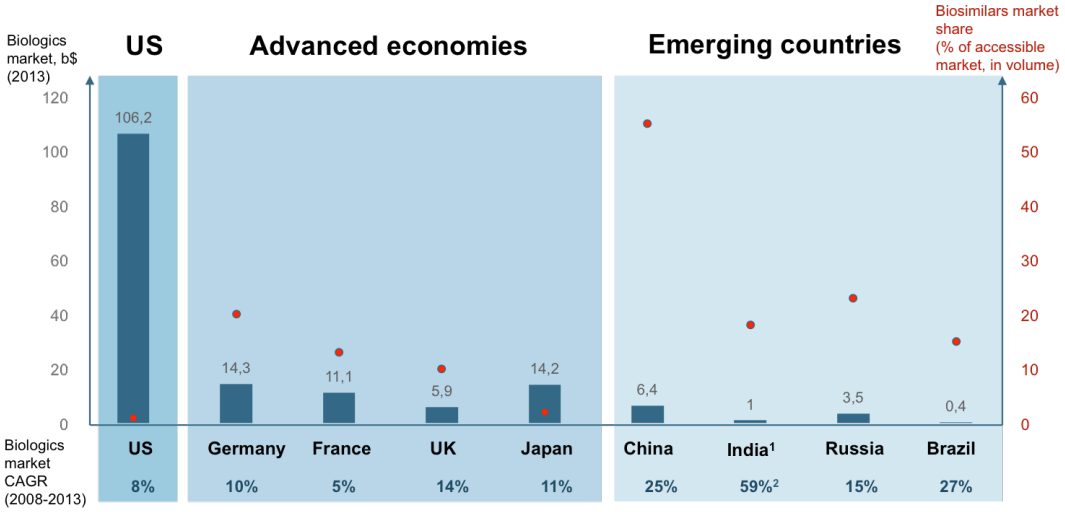

Fig. 1 – Biologics market and market shares of biosimilars, by region (Source IMS 2011)

These molecules are more complex and difficult to develop and to produce. Moreover, no biosimilar will ever be the exact same molecule as the one it aims to copy: biologics are composed of millions of atoms and the slightest modification of their manufacturing process is bound to lead to structural differences in the end product. The beginnings have been difficult for some of the early entrants: Teva had to discontinue their rituximab biosimilar trials in phase III, several manufacturing partnerships on insulins have been terminated, to mention just a few examples.

[1] Source IMS Health

Regulators have therefore been very prudent in delivering market authorizations to these copies. While Europe has opened the way as early as 2005 by introducing a regulatory framework encouraging the development of biosimilars, it has taken 10 years to the FDA to follow suit.

Commercially as well, it turned out that taking market share from the established players required significant marketing power, which new entrants did not have. Physicians were reluctant to prescribe these new drugs, which were not identical to those they knew, and not that cheaper. Why should they take the risk?

10 years after the first launch, cumulative biosimilar sales over the 2001-2011 period were only $ 1.2b, while total development costs had already reached more than $ 1.5b.

2015: a new era

In the last 12 months, however, the situation has changed dramatically, for several reasons:

- During the next 5 years, a large series of top-selling biologics will lose patent exclusivity, opening a market of $ 65b to biosimilars (vs $ 2.5b in 2014)
- The gate to the US market is now opening: the FDA has issued a regulatory framework on biosimilars. After authorizing the first biosimilar of Somatropin, they are currently reviewing the second one (infliximab, sales of $ 7b in 2012). In Europe, infliximab is being launched in all countries this year
- Top-class biologics manufacturers such as Amgen have decided to join the race and are currently developing biosimilars of their competitors. This will create intense competition and boost the market
- Under increasing financial pressure, payors around the world are attracted by the savings potential and are encouraging the penetration of these new drugs. Germany has imposed quotas of biosimilars on certain classes, Norway is funding a national clinical study on patients switching from Remicade® to Orion Pharma's biosimilar, Remsima®, to demonstrate safety and efficacy of biosimilars.

It seems that a turning point has now been reached: biosimilars are set to take off. By 2025, if all barriers are removed, sales of these new drugs could reach as much as $ 35b. Will we go that far? Who will win the race?

Different players, with different objectives

3 types of players will fight for this market:

1. Historic generic players who are looking for new sources of growth, such as Sandoz, the current market leader, and Teva
2. "Pure players", i.e. new entrants who have developed bioproduction capabilities to specifically address this market, such as the American Hospira (recently acquired by Pfizer) and the Koreans Celltrion, Samsung and Hanwha
3. Established, big pharma players, such as Amgen, Pfizer and Sanofi, who have decided to enter this area for different strategic reasons. Amgen wants to capitalize on their expertise in biologics, both from a manufacturing and a commercial point of view, to grab a share of the cake; Pfizer sees in biosimilars an opportunity to generate further growth; Sanofi, which is just playing in its own insulin market, seems to be pursuing a more defensive strategy.

What will be important to succeed?

Who will be the winners in this new market? Clearly, manufacturing will be a key success factor. The highest quality standards will be demanded by patients, prescribers and authorities, as well as a perfectly reliable supply chain, which is not a given for such complex molecules.

The second challenge will be to convince prescribers and payors. Prescribers will want to see real-life switch data, and payors need to see the savings. The example of Remsima® shows an innovative, win-win form of contracting.

Pricing will be a strategic issue as well. Originators have a cost advantage over newcomers, and may be tempted by "predator pricing". However, payors may not let them do that and may set quotas for biosimilars in key markets.

Getting prepared

Whether they are in an offensive or defensive position, all players must now get prepared to face the key challenges of this new market. Beyond product quality and supply reliability, which will be mandatory, we believe all players must get prepared on 3 key topics:

- **Data generation**: how can real-life data be generated as quickly as possible to convince prescribers?
- **Pricing and contracting**: what deal structure can be proposed to payors in order to secure a successful entry (rebates against data, pay for performance,…)?
- **Field organization**: who should be targeted by commercial teams on the field, and how, and how long after launch, to ensure maximum demand generation?

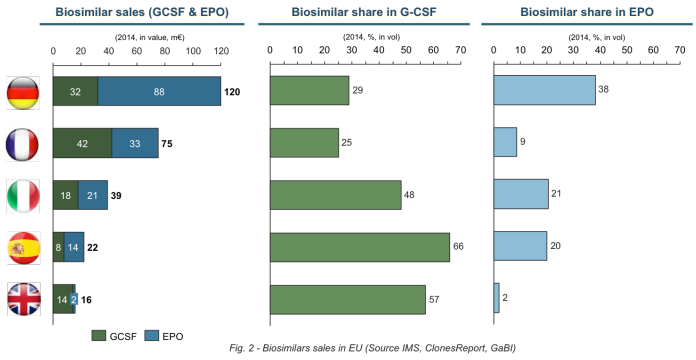

Fig. 2 - Biosimilars sales in EU (Source IMS, ClonesReport, GaBI)

One thing should be remembered: **there will not be one single biosimilar market**.

Switches from the originators to the new biosimilars will go fast in some diseases, slowly in others. Local healthcare systems will also have a strong influence: in each country, prescribers and payors will behave differently, and will have their own decision-making processes.

From the "national tender" system in Norway to the more prescriber-driven decision-making in France, successful players will need to adapt their commercial strategies and organizations.