Are the learnings from the introduction of biosimilars in inflammatory diseases in Europe transferable to the future introduction of biosimilars in oncology?

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Background

Payers and other stakeholders are looking for ways to generate cost savings. The unsustainable growth in healthcare costs, issues in affordability and arrival of higher value, more expensive therapies are continuous and growing concerns. Thus, the cost-savings potential offered by biosimilars has resulted in a dynamic and fast-changing market.

GfK looked at the biosimilar market in three distinct waves (figure 1):

- Wave 1: EPO, G-CSF, HGH
- Wave 2: Inflammatory diseases
- Wave 3: Oncology

A retrospective analysis of the Wave 1 biosimilars showed a significant difference in biologic uptake between products and countries (figure 2). This can be largely explained by the differences between products and countries in three key areas: pricing strategies of the originators (proactive vs. reactive), distribution channels (hospital vs. retail) and the variation of the purchasing/procurement/tender systems and their parameters.

When combined with a relatively low budget impact, strict regulations and requirements around biosimilars was limited in Wave 1. In contrast, stakeholders prepared for Wave 2 – the inflammatory space – where the opportunity for cost savings (payer perspective) and revenues (pharma perspective) was so much higher. The market dynamics around uptake evolved and became more complex.

As the availability of biosimilars expands into oncology, stakeholders will be keen to realize an even larger cost-savings potential. While they will lean heavily on what has been established in the inflammatory space and not “re-invent the wheel”, greater nuances will be keen to realize an even larger cost-savings potential.

Thus, it will be important for oncology biologic manufacturers to understand what dynamics and learnings they can apply from the inflammatory space, but also what new opportunities and challenges should be considered.

Objectives

- To establish the key drivers of procurement, pricing, access, and uptake (PPAU) for biologics in inflammatory diseases where biosimilars, bio-origins and new innovative biologics compete.
- To explore the likely future drivers of PPAU in oncology when biosimilars enter the market.
- To identify commonalities and differences between the disease areas.

Methods

- The research focused on three anti-TNFs used in inflammatory diseases (infliximab, etanercept, adalimumab) and three oncology products (trastuzumab, bevacizumab, rituximab).
- For the Wave 1 biosimilars, the historical evolution of pricing and uptake across products and EU countries was analyzed and included in the background information.
- For the Wave 2 biosimilars, the research focused on three anti-TNFs used in inflammatory diseases (infliximab, etanercept, adalimumab). A retrospective analysis was conducted across all studies (n=119) undertaken by GfK since January 2014 involving the pricing and market access of biologics in Europe in inflammatory diseases. The studies involved primary research, system dynamics modeling and war gaming (competitive simulation). The drivers of procurement, pricing, access and uptake (PPAU) were identified.
- For the Wave 3 biosimilars, three oncology products (trastuzumab, bevacizumab, rituximab) were included. A focus-group approach was used to predict the likely future drivers of PPAU in oncology following the introduction of biosimilars. The forces of supplier and buyer power, impact of new entrants, impact of substitutes and competitive rivalry were explored.

Results

Wave 2: The multi-methodology analysis of Wave 2 biosimilars indicated that the biggest drivers of biosimilar PPAU are driven by:

- Physician willingness to switch or initiate new therapies
- New entrants / competitive rivalry
- Overall reduction in pricing, access and uptake

Conclusions

- The experience with inflammatory disease biosimilars does not translate directly to oncology biosimilars.
- The lower costs associated with the arrival of biosimilars in oncology may increase the market access opportunities for targeted therapies, immunotherapies and combinations of high-priced/high-value cancer drugs.
- Higher disease severity and specialized approaches to treatment decisions will result in a slower rate of change in PPAU for the oncology market compared to immunology.
- Manufacturers (originators and biosimilars) in the oncology spaces where biosimilars are entering should focus on:
  - Establishment of an appropriate positioning within pan-European, national and local treatment guidelines
  - Establishment of an appropriate positioning within the emerging Value Frameworks
  - PR/policy-influencing strategies communicating the opportunity for better survival outcomes in cancer patients by cost savings being released to allow (more) patients to be treated with more effective products
  - Potential to influence the introduction of biosimilars to increase cost-benefit ratio or create budgetary leeway, addressing potential financial issues
  - Innovative pricing propositions that address the way that expensive hospital products are procured (e.g. by leveraging portfolio selling opportunities)


2. IMS MIDAS. 2016. Europe defined as EU28 plus Norway and Switzerland and excluding Malta and Cyprus, whereas IMS Health does not have an audit. Pharmaceutical sales valued at ex-manufacturer price, excluding the impact of rebates and discounts

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