

# Biosimilars: HGHs to TNFs, how will payers respond?

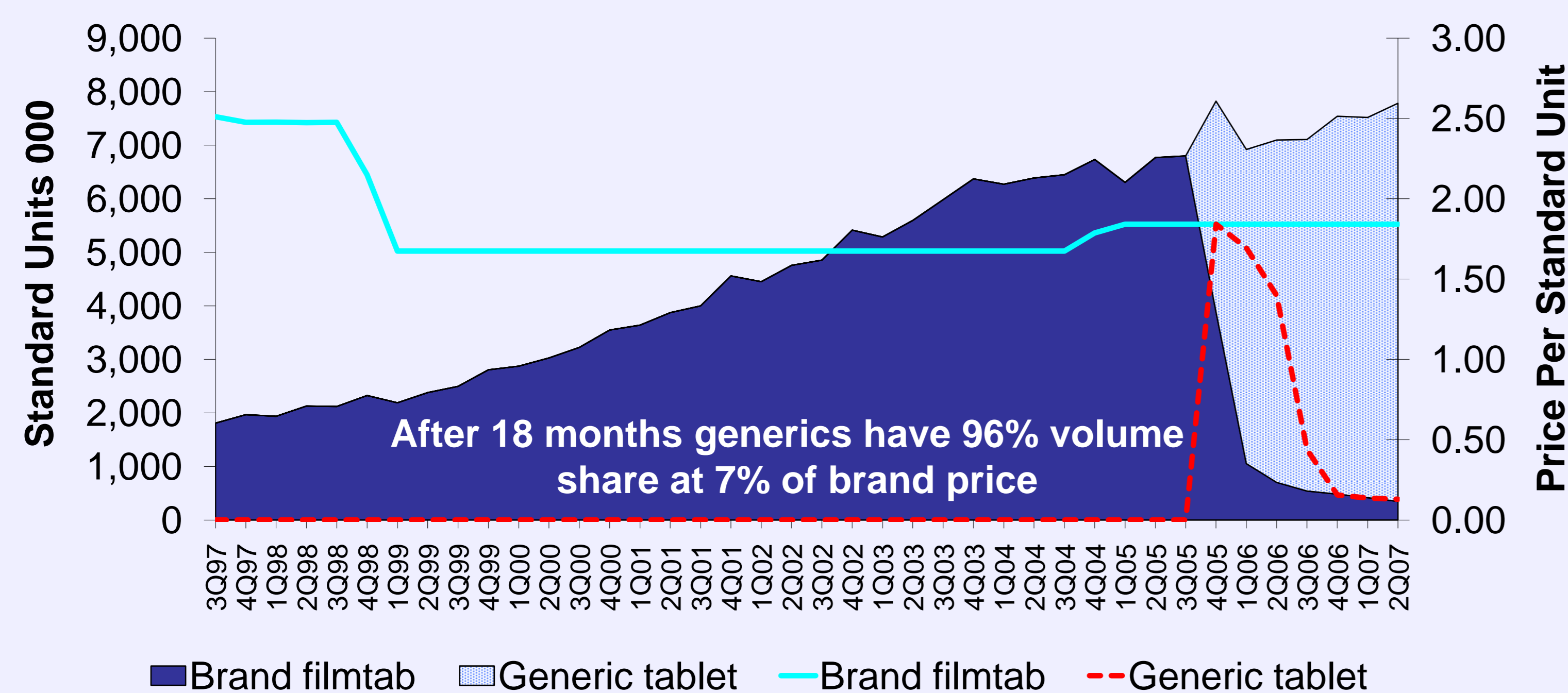
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PriceSpective, www.pricerspective.com

## Objectives

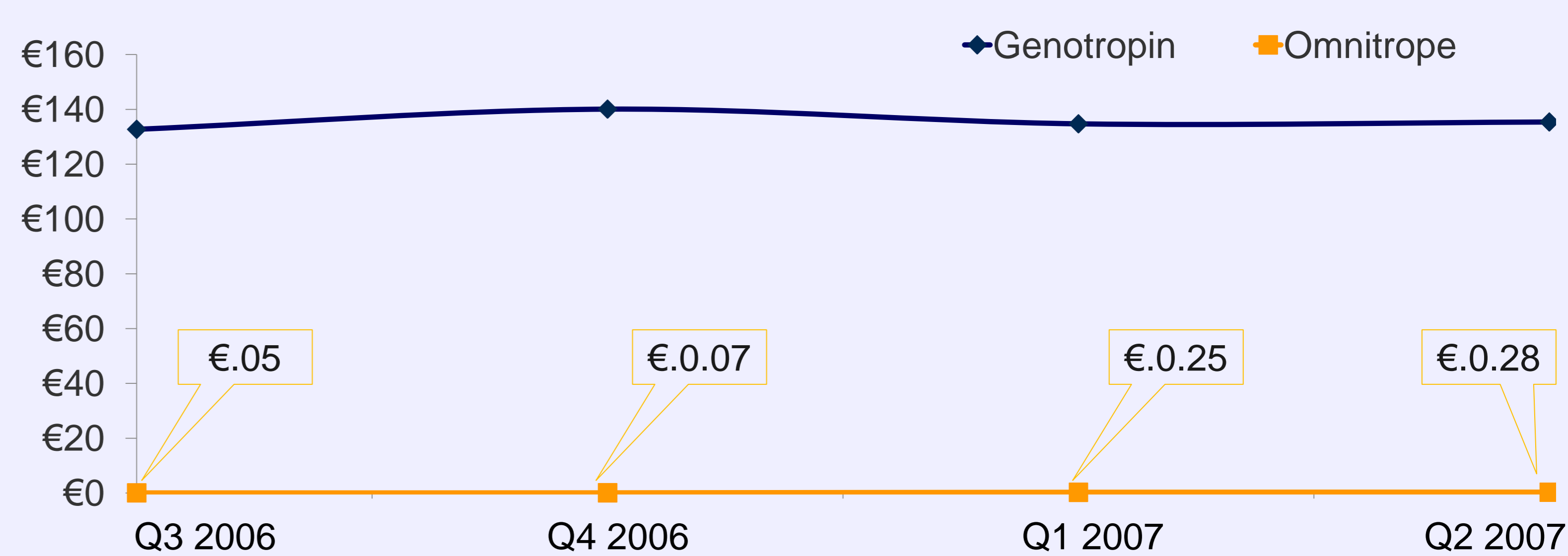
Biologic agents have helped revolutionize the treatment of a number of chronic and acute diseases. These highly valued products have also placed a significant cost burden on healthcare systems. Payers, understandably, are eagerly awaiting the arrival of biosimilars. However, because of their biologic nature, biosimilars are not exact copies of the originator brands. This important difference between biosimilars and traditional generics has resulted in greater requirements for regulatory approval and has led some markets to take positions on their (non) interchangeability. Given these dynamics, this research explores the likely price discounts of anticipated biosimilars, provides an analysis of what lessons can be taken from traditional generics and forecasts how biosimilars might change the standard of care for their respective therapy areas. Germany is used as a common reference market because it is currently the market most open to biosimilars.

## Results

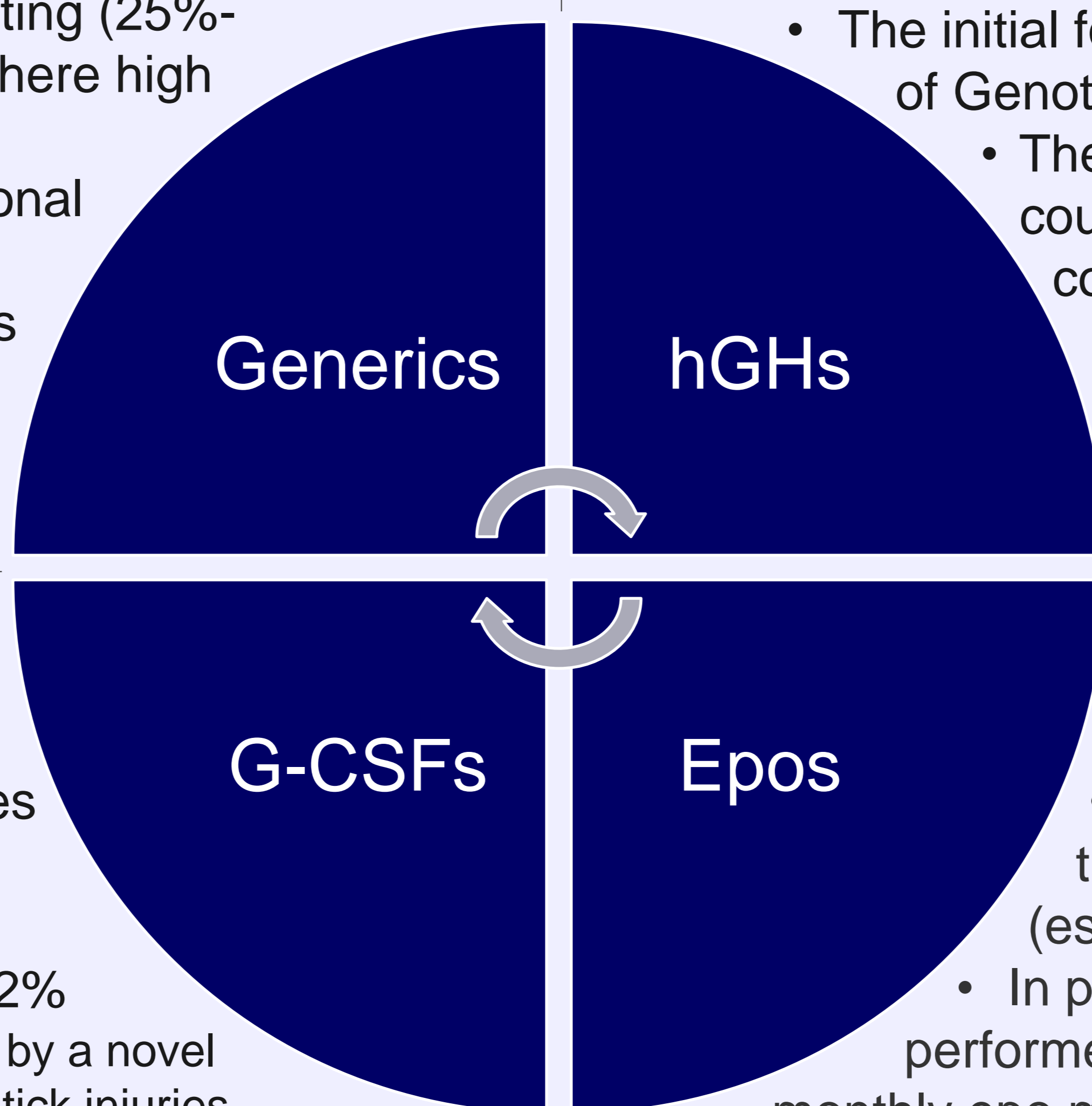
Example of Generic Price and Market Share Erosion in the UK<sup>1</sup>



Global Omnitrope Uptake in Sales (Euros, millions)<sup>2</sup>

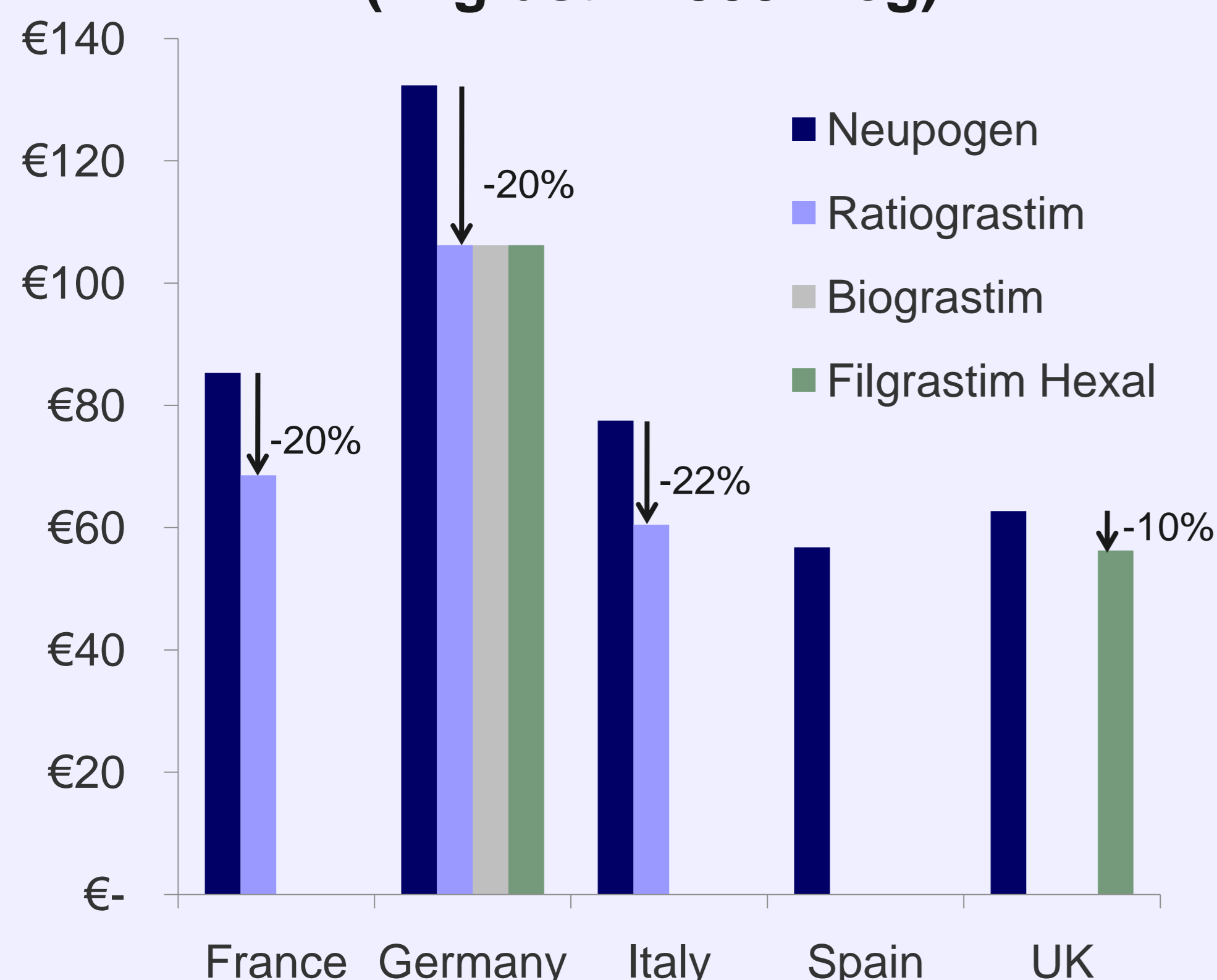


- Payers in Europe have seen generics as a means of cost-savings; while some EU markets have higher generic utilisation than others, generic uptake is generally increasing across Europe
- This is largely driven by the level of generic discounting (25%-40% in the EU5); an extreme example is the UK, where high selling products see discounts of over 80%
- France, Italy and Spain have pricing rules for traditional generics; however, because of the uniqueness of biosimilars, they are unlikely to fall under these rules
- At least 15 markets in Europe have rules or regulations that prevent automatic substitution with a biosimilar (including the EU5)
- Five filgrastim biosimilars were granted marketing authorisation by the EMEA in 2008-2009
- To date, three of the five approved biosimilars have been launched in Germany, where generic medicines are most accepted; in the rest of the EU countries, either only one or none has been marketed
- The level of discount to Neupogen varies from 10-22%
  - Further, one of the biosimilars, Zarzio, is differentiated by a novel needle safety device that is intended to avoid needle stick injuries
- It is too early to judge uptake given the continuing launch of products. Biosimilars are likely to have a negative impact on Neupogen sales, but, a range of opportunities and challenges may affect the market dynamics



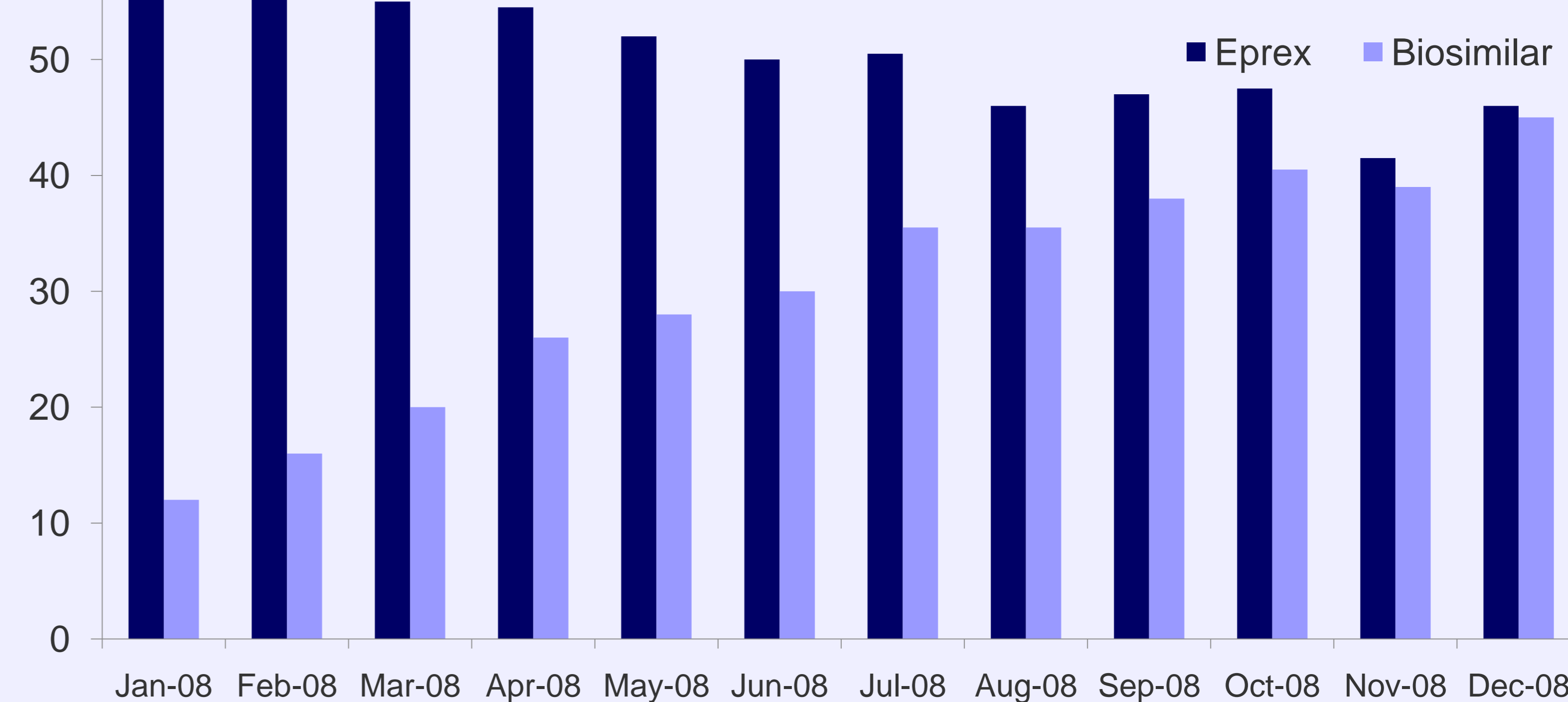
- Omnitrope (biosimilar of Genotropin) the first biosimilar approved in the EU in April 2006 and was launched first in Germany
- The range of discounts seen in the EU were 20%-25% at launch
- Uptake of Omnitrope was slow upon launch given the familiarity and flexibility of using Genotropin among physicians
  - The initial formulation of Omnitrope outsold the comparable size of Genotropin likely driven by the discounts for that dose size
  - The hGH market has been difficult to penetrate in all countries given the young patient population and concerns for long-term safety for use in these patients
  - Discounts in hGH have been in line with expectations for biosimilars, but other therapy areas that are more commoditized, may need larger discounts than those seen in hGH
- Biosimilars of Eprex were approved in 2007
  - The current level of discount for biosimilar epoetin alfas range from 11%-30%
  - Epo biosimilars have had a much more rapid uptake than hGH biosimilars but sales are still relatively small (estimated at 5% of the epo market across Europe)
  - In part because of formulary inclusions, epos have performed the best in Germany, capturing 14% of the total monthly epo market
- Biosimilar epos entered an already highly commoditized market (e.g., in the UK, competitive hospital tendering resulted in discounts of 70% prior to biosimilar entry); this has put additional pricing pressure on epos and has contributed to Medice's (manufacturer of epo biosimilar Abseamed) efforts to find marketing partners in EU markets

Manufacturer's Selling Price<sup>3</sup> (Filgrastim 300 mcg)



- As the therapy area is under budget scrutiny, the price differential to Neupogen may be well received
- At the regional/local level, purchase negotiations and the resulting net lower price may impact guidelines on use of the cheapest filgrastim for new patients

German Market Share (IU units, Millions)<sup>4</sup>



Sources: <sup>1</sup>PriceSpective; <sup>2</sup>King, Michael G "Biosimilars 2008: View from Wall Street" Rodman and Renshaw, downloaded October 11 2009; www.ihsglobalinsight.com/SDA. Accessed October 18, 2009; <sup>3</sup>Prices accessed at www.theriaque.org, www.rote-liste.de, www.petrone.it, www.healthcarepublic.com; <sup>4</sup>Hospira Responses to FTC Questions on Biosimilars (May 2009) accessed at http://www.ftc.gov/os/comments/healthcarecompissues/090519hospirasupplementonbiosimilars.pdf

## Conclusions

Biosimilars will introduce a new competitive dynamic to the biologic market. However, because of the considerably higher cost of bringing biosimilars to market and the potential to differentiate biosimilars (e.g. better delivery device), the initial price discount will be more similar to a 'me-too' like pricing strategy as opposed to what has been seen with competitive generic markets. In Europe, the emerging pattern with currently available biosimilars suggests that even at 20-30% discount levels, national authorities across markets are unlikely to mandate biosimilar use over branded products at least initially and for greater uptake, physician confidence with the efficacy and safety of the new molecules are required. The market dynamics for TNF biosimilars will be further complicated as TNFs are more complex molecules than the already available biosimilars necessitating greater investment and development risks. As a result, there are likely to be fewer biosimilar entrants, potentially limiting steep discounts observed when there is competition of multiple products. In addition, physicians will be cautious with use of new molecules due to the irreversible nature of disease in rheumatoid arthritis, the largest market for TNFs. Given physician concern, payers are unlikely to advantage biosimilars or implement access hurdles for branded TNFs solely due to price considerations. This is also the expected result in the US. However, the net price of biosimilars vs. branded agents to MCOs may impact tier placement and patient co-pays.