Potomac Research Group

Follow-On Biologic Market: Initial Lessons and Challenges Ahead

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INSTINET. Research Partners

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- The emerging follow-on biologic markets suggest lower discounts and less market penetration than for small molecule-based medicines.
- Key differences between the small-molecule and the biologics market.
- 3 backstops against rapid reference product market share erosion: insurance reimbursement incentives, evergreening, and safety concerns about substitution.

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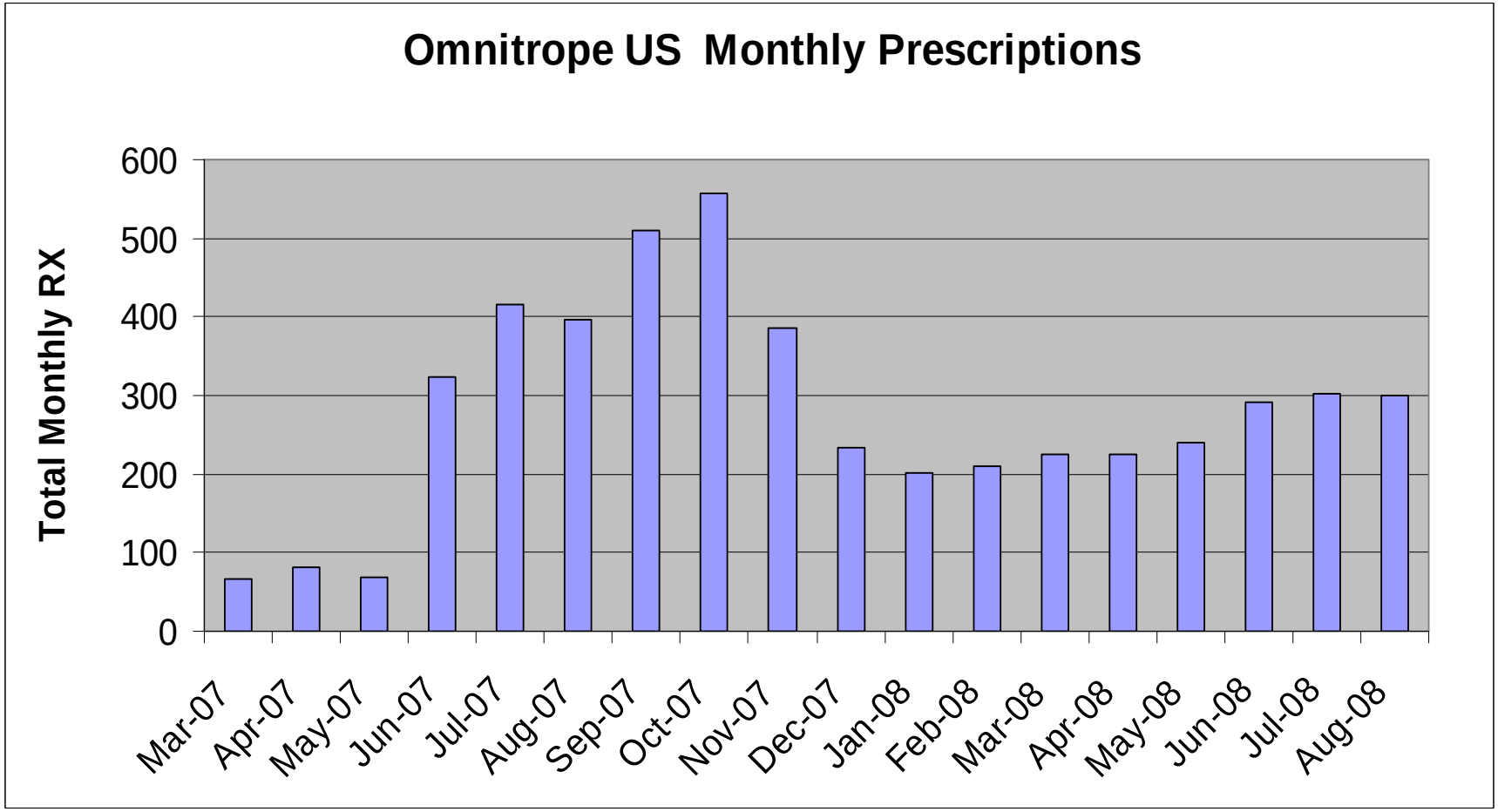
THERE IS A MARKET FOR BIOSIMILARS….



Source: IMS Health

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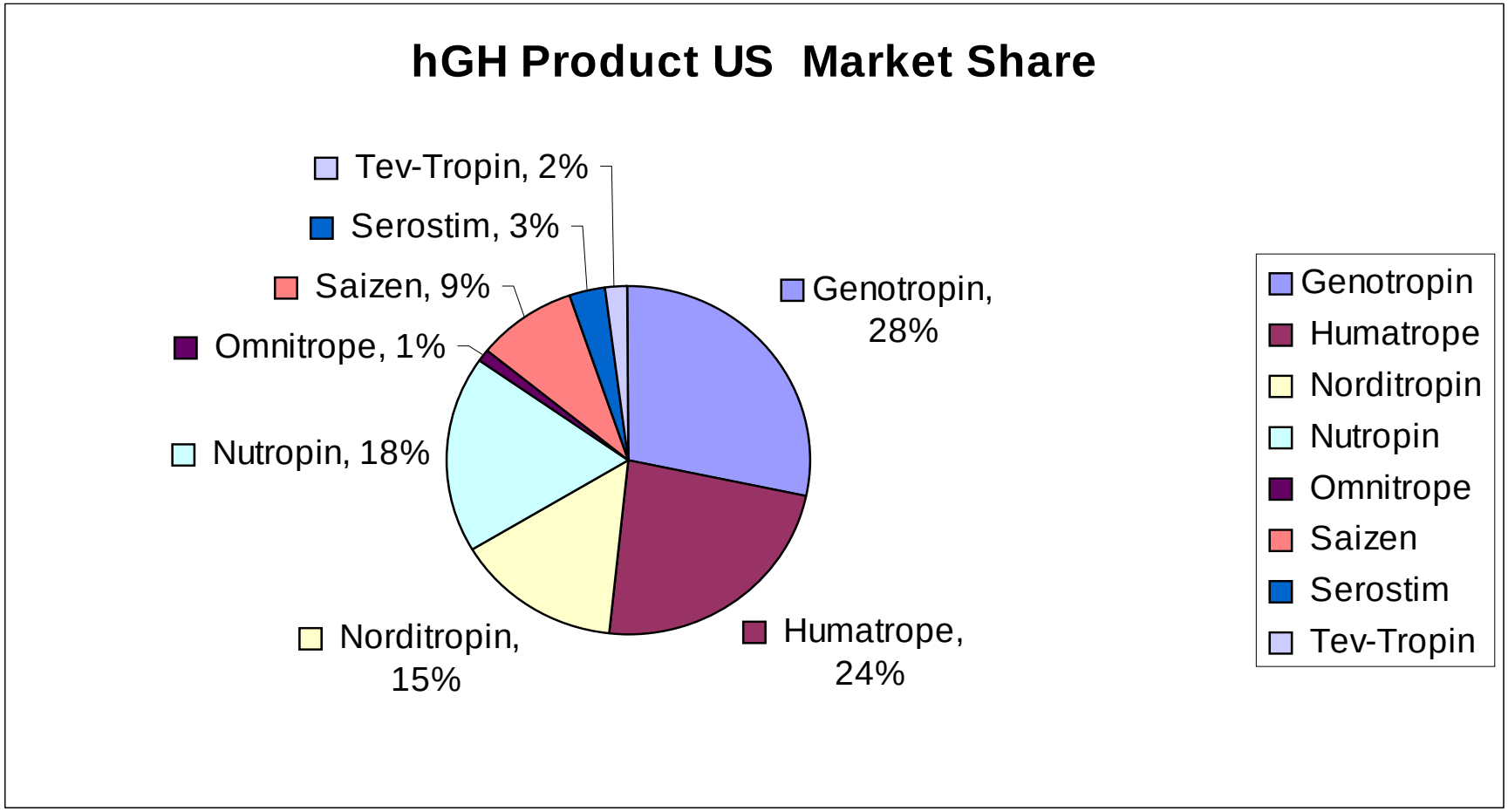
…BUT LIMITED IF BIOSIMILAR USES A DIFFICULT ROUTE OF ADMINISTRATION



Source: IMS Health

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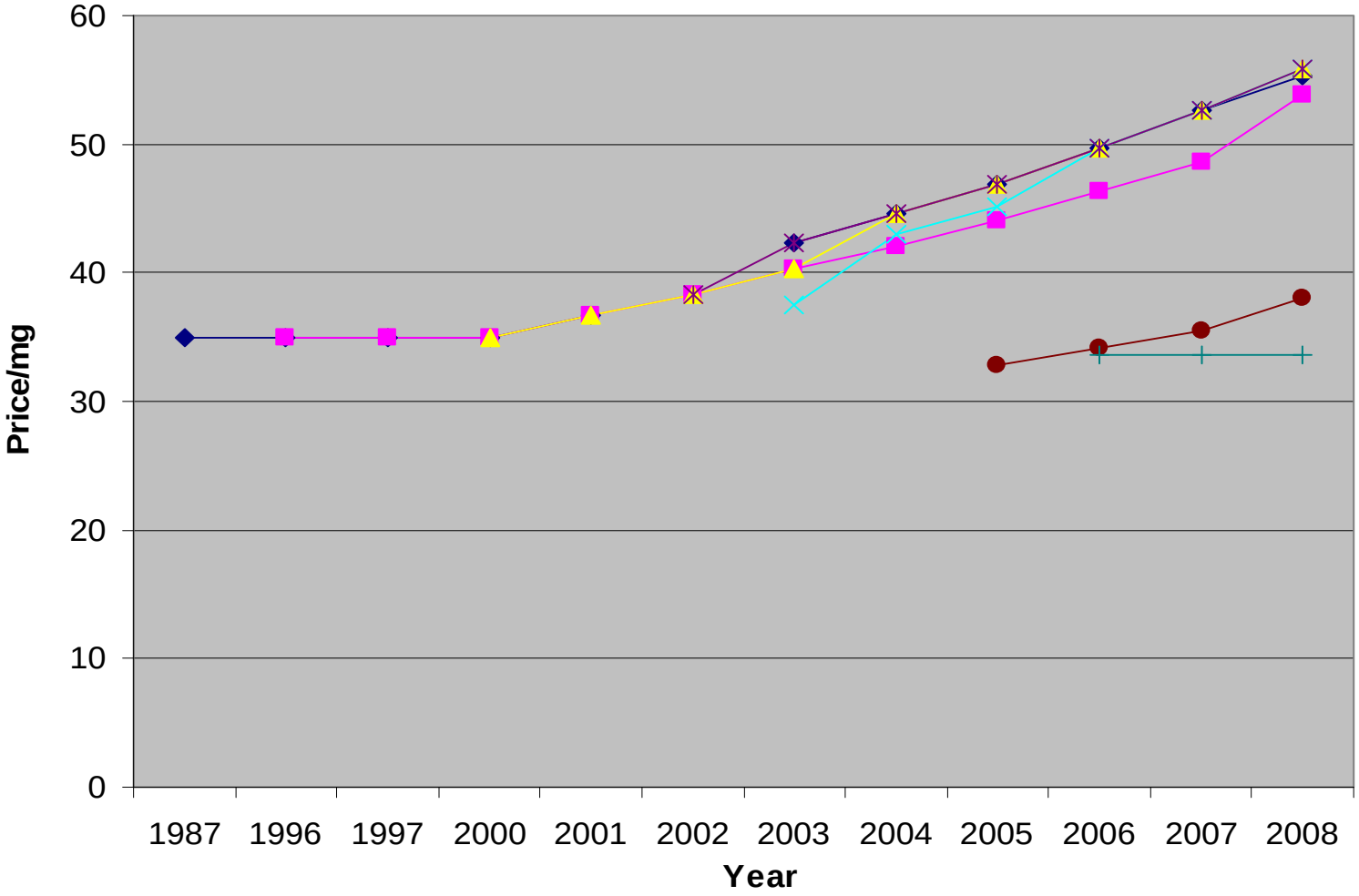
Somatropin WAC prices in the US: Prices of all the somatropins have increased even after the addition of new products



Data source: IMS, as compiled by Sandoz, a Novartis company

Pricing of Somatropin

- Initial discount of about 30% for Omnitrope in comparison to Pfizer's Genotropin in 2006, based on wholesale acquisition cost (WAC).
- Discount widens to about 40% in 2008 as Omnitrope competitors raise prices, compared to 80% discounts in the market for traditional medicines.
  - Aggressive discounting not calculated in WAC may help innovators maintain market share

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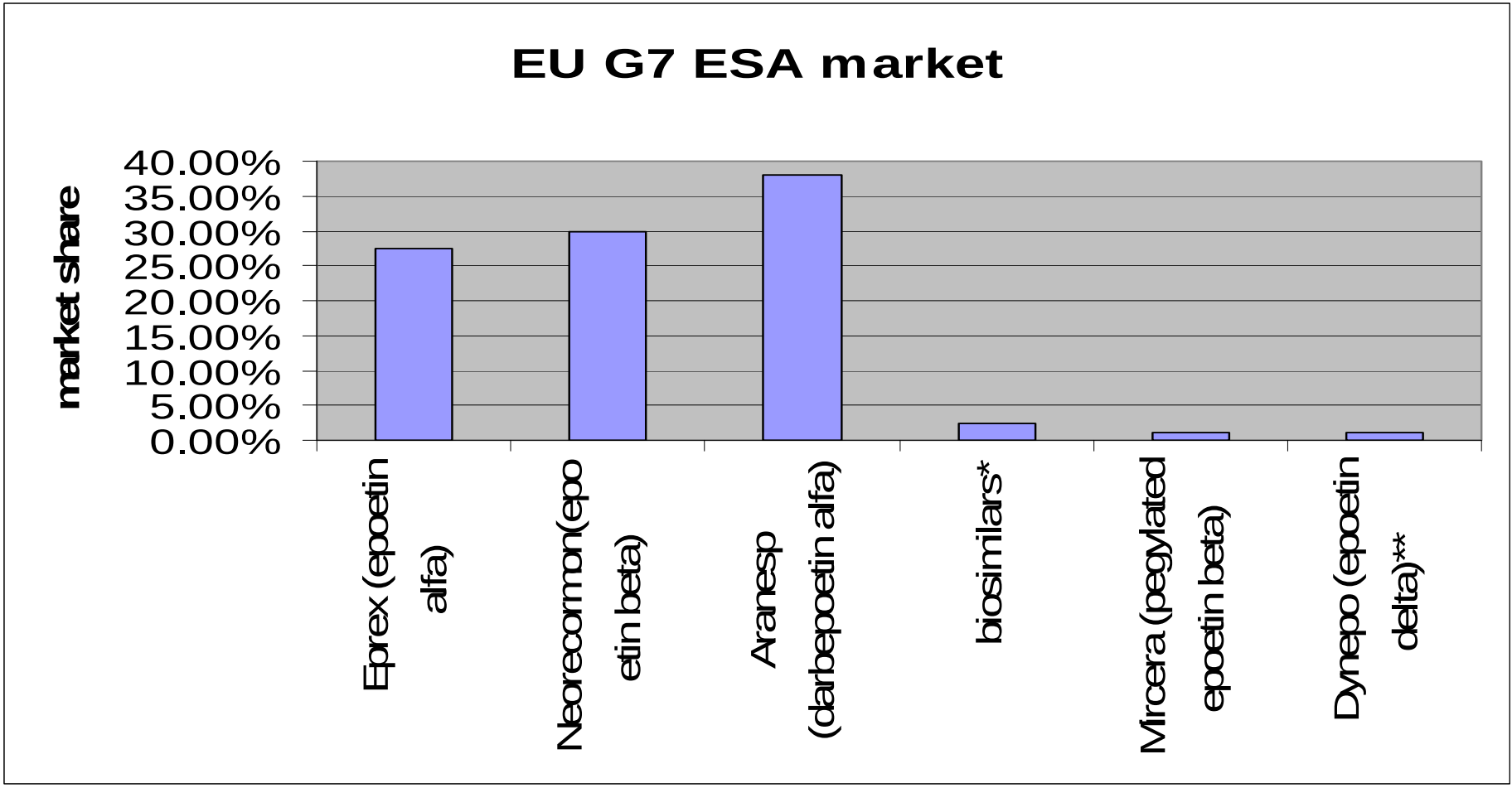
ESA BIOSIMILAR MARKET STARTS SLOWLY AS WELL



Source: IMS Health and companies

*Biosimilar market share just in Germany and UK.
**Dynepo being phased out by year end.

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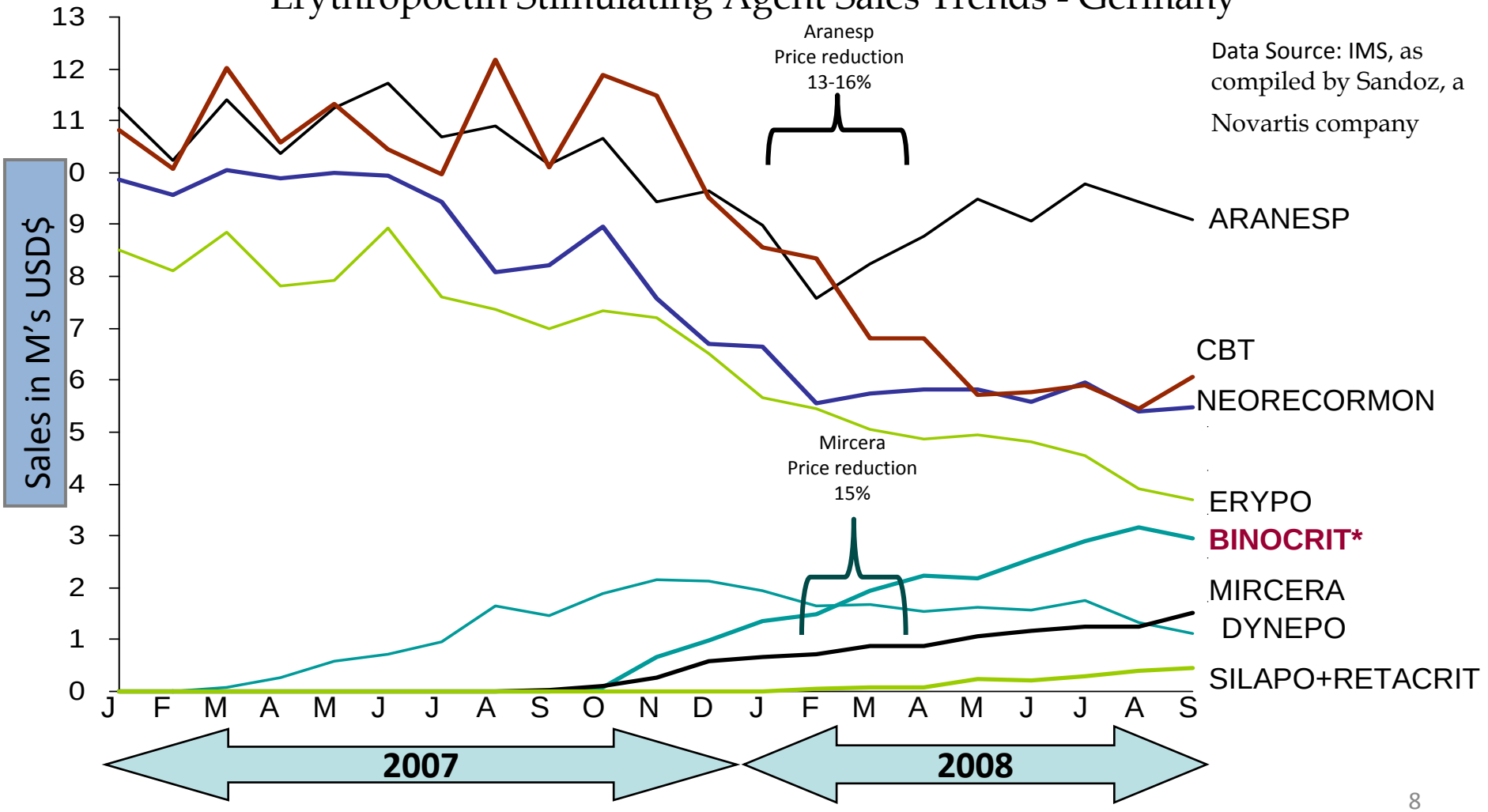
Erythropoetin Stimulating Agent Sales Trends - Germany



* Represents Binocrit, Epoetin alfa Hexal and Abseamed

Biosimilar Discounts Significant

- ESA brand-name competitors reduce prices before and after introduction of biosimilars in Germany and UK.
- Amgen reduces price 13% to 16% in early ’08 in Germany. However, Amgen says it maintains a 15% to 30% price premium to first generation ESAs in Europe. Other data suggest price premium is narrower in Germany.
- ESA biosimilars priced at about 25% discount to innovator product.

Sources: IMS and companies

Causes of More Limited Biosimilar Market

- Clinical development and marketing costs.
- Biosimilar NOT substitutable for reference product at retail pharmacy level
  - State generic substitution laws may not provide for biosimilar or biogeneric substitutability.

One Man'sTech Gain is Another's Evergreening

- Introduction of 2nd generation product threatens to limit potential of biosimilars to save money by retaining reference product market share and price premium.

  Aranesp:

  - Still commands a premium price to first-generation ESAs, according to Amgen, although that premium is narrower in Germany.
  - Remains market leader in sales, with less market-share erosion in Germany than first-generation ESAs.

- Caveat: Biosimilar may improve on the reference product.

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Biosimilar Impediment: Reimbursement Incentives

- 64% of biotech drugs are used in a physician's office which limits effectiveness of retail pharmacy substitution (if its even possible).
- Medicare Part B payment system provides incentive for doctors to use the more expensive drug.
- Limits on Medicare's authority to group similar drugs in same payment category.
- Can Medicare use coverage decisions to steer patients toward biosimilars?

Some Insurance Incentives in Place

- Dialysis bundling (although payments not yet set)
- Insurance plan formularies
- Medicaid preferred drug lists

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Conclusions

- First biosimilars in Europe and US show potential for price discounts, but more modest than with small-molecule generics.
- Federal and state legislative issues of substitutability, public and private reimbursement incentives and coverage, and coding authority are key to future of biosimilars.

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