Follow-On Biologic Market: Initial Lessons and Challenges Ahead

Paul Heldman
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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.
THERE IS A MARKET FOR BIOSIMILARS….

Source: IMS Health
...BUT LIMITED IF BIOSIMILAR USES A DIFFICULT ROUTE OF ADMINISTRATION

hGH Product US Market Share

- Genotropin, 28%
- Humatrope, 24%
- Nutropin, 18%
- Norditropin, 15%
- Omnitrope, 1%
- Saizen, 9%
- Serostim, 3%
- Tev-Tropin, 2%

Source: IMS Health
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
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.
Erythropoetin Stimulating Agent Sales Trends - Germany

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

ARANESP
CBT
NEORECORMON
ERYPO
BINOCRIT*
MIRCERA
DYNEPO
SILAPO+RETACRIT

* 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’s Tech 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.
Biosimilar Impediment: Reimbursement Incentives

- 64% of biotech drugs are used in a physician’s office which limits effectiveness of retail pharmacy substitution (if it’s 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
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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For more information contact Paul Heldman at 202-266-7289.

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