Pharmacoeconomic Modeling of Biosimilars in the US: A Conceptual Framework

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Background & Purpose
- Biosimilars’ introduction in the US market heralds a new era in the management of many diseases.
- The impact of biosimilars on clinical and payer landscapes is uncertain.
- We developed a conceptual framework to provide guidance in modeling biosimilars and estimating their pharmacoeconomic value in the US setting.

Conceptual Model Framework
- We leveraged existing modeling methodology, experiences from the US generics and EU biosimilars markets, and expert opinion to establish recommendations for addressing challenges.
- We identified key challenges in modeling biosimilars around 3 fundamental components that differentiate biosimilars from other pharmaceutical products:
  1. Price
  2. Interchangeability & Indications
  3. Market Share

Price Lessons from US
- Generic small molecule market:
  - 50%-80% price declines
- Discounting
- Varying prices with sites of service:
  - Hospital vs. physician office
- Self-vs. physician-administered

Price Lessons from EU Biosimilars
- Average: 25% declines
- Dependent on:
  - Country, healthcare system structure
  - Next-generation biologic competition
  - Acute vs. longer-term use

Price Recommendations
- Model price estimates could be based on:
  - Product- and setting-specific predictive modeling
  - Assuming 35% biosimilar discount 10 years post-market entry (range 10%-40%)
  - Interactive models: user-modifiable price estimates
- All models: sensitivity analysis with wide CIs to reflect uncertainty

FDA DECISIONS: INDICATIONS & INTERCHANGEABILITY
- Challenges – Biosimilar:
  - Indications may differ from those of reference biologic
  - May not be considered interchangeable with reference biologic
  - Substitution may require additional administrative tasks (e.g., notification)
  - Prior authorization
  - Prescriber notifications
  - Medication management
  - Uptake may be affected
  - Reliability of adverse event data may be impacted (e.g., due to pharmacovigilance issues)

Indications & Interchangeability
- Models for publication, include biosimilar:
  - Off-label use, when appropriate
  - In separate scenario analyses
- Proactive models: include approved indications

MARKET SHARE
- Challenges – Price, indications, and interchangeability:
  - Direct impact market share
  - Fluctuate over time:
    - Branded biologic price 
      - with biosimilar competition
    - Overall biologics market growth
  - Biosimilar price, interchangeability, indications, biosimilar penetration
  - Complex interactions:
    - Price, indications, and interchangeability

MARKET SHARE

Conclusions
- Estimating biosimilars’ pharmacoeconomic impact in US:
  - Price: assume 35% discount relative to reference biologic
  - Market share: growth to ~60% over 10 yr
  - Vary with: indications, time period
- This framework provides guidance for:
  - Payers – planning budgets, formularies
  - Physicians – planning patient care

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