Pharmacoeconomic Modeling of Biosimilars in the US: A Conceptual Framework

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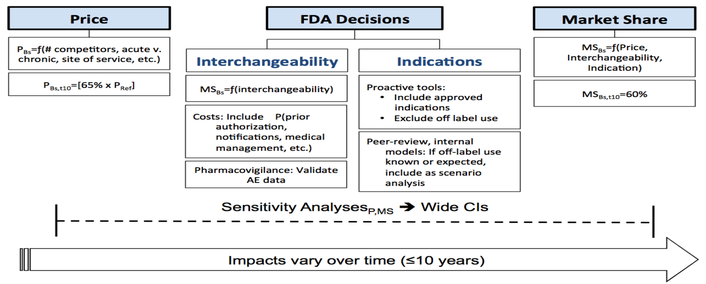
Background & Purpose

- 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:

Price | **Interchangeability & Indications** | **Market Share**



f=function; AE=adverse event; BS=biosimilar; CI=confidence interval; MS=market share; P=price, Ref=reference (branded) biologic; t10=10 years post market entry.

PRICE

Challenges: Biosimilar prices uncertain: before & after market entry

- Prices driven by complex factors: discounting, competition, indications, setting, etc.
- Potential price sources for models:
  - US generics
  - EU biosimilars

Price Lessons from US	Price Lessons from EU Biosimilars
▪ Generic small molecule market: – 50%-80% price declines – Discounting ▪ Varying prices with sites of service: – Hospital v. physician office – Self- vs. physician-administered	▪ 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%)[1]
- Interactive models: user-modifiable price estimates
- All models: sensitivity analyses with wide CIs to reflect uncertainty

1. Mulcahy AW, et al. *Perspective*. November 2014. The RAND Corporation. Available at: http://www.rand.org/content/dam/rand/pubs/perspectives/PE100/PE127/RAND_PE127.pdf.

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 (& thus **costs**), e.g.:
    - 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 Recommendations:

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

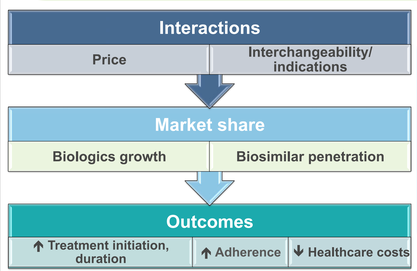
Internal models, publications	Field tools
Case-by-case	*Approved indications*
Scenario, sensitivity analyses	*Exclude off-label use*

MARKET SHARE

Challenges – Price, indications, and interchangeability:

- Directly 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 ➔ ↓ OOP costs ➔ ↑ treatment duration, adherence ➔ ↑ outcomes, ↓ disease costs

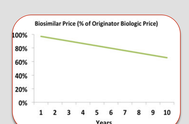


Recommendations:

Interactions, Indirect Impacts	Timing
Price-market share interactions	*Model inputs not static over time*
60% biosimilar market penetration[1]	*Changes up to 10 years*

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



1. Price: 35% ↓ (SD: 10%-40%)

2. Market share: 60% (SD: 10%-90%)

3. Varying impact over ~10 y

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