Medication Sector in Qatar: Hand in Hand Facing the Blockade

Economic Opportunity: Brand Drugs vs. Generic Drugs
Daoud Al-Badriyeh, PhD
Economic Opportunity:
*Brand Drugs vs. Generic Drugs*

- Disclose of Conflict of Interest -

Disclaimer:
Presenting Authors Have No Relationships to Disclose
Economic Opportunity: Brand Drugs vs. Generic Drugs

- Pharmaceutical markets in the Middle East region are attractive.

- The high spending on branded drugs is unsustainable.

- Publicly funded health systems – increased pressure to reduce rising drug budgets.
Originator (NDA) vs Generic (ANDA) review process requirements
- 20-90% cheaper generics

<table>
<thead>
<tr>
<th>NDA Requirements</th>
<th>ANDA Requirements</th>
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<tbody>
<tr>
<td>1. Labelling</td>
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<tr>
<td>2. Pharmacology/Toxicology</td>
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<td>3. Chemistry</td>
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<td>5. Controls</td>
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<td>7. Inspection</td>
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<td>8. Testing</td>
<td>8. Testing</td>
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<td>10. Clinical Studies</td>
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<td>11. Bioavailability</td>
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The generic drug industry is responsible for making more affordable and cost-saving medicines
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- **USA, as example:**
  - 1980 – 17.3%
  - 1990 – 32.0%
  - 1997 – 43.0%
  - 2009 – 63.5%
  - 2016 – 89.0%

- Generics share in Qatar: 22%
- Average share in Middle East: ~28% (6% - 70%)
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Market share (Value)
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- In USA, as example, in 2007-2016, $1.7 trillion ($5 billion/week) were saved.

- In Canada, $50,000 reduction in ICER per outcome.
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- Mental Health: $44 Billion
- Hypertension: $29 Billion
- Cholesterol: $28 Billion
- Anti-Ulcerants: $22 Billion
- Nervous System Disorders: $16 Billion
- Pain: $13 Billion
- Cancer Anti-Nauseants: $11.8 Billion
- Oncology: $10 Billion
- Anticoagulants: $9.1 Billion
- Antibacterials: $8.8 Billion
- Respiratory: $7.4 Billion
- Diabetes: $5.5 Billion

Cost saving with generics
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• HOWEVER, economic savings are not guaranteed
  • Evaluations of economic impact of generics are mostly based on acquisition costs, **NOT disease cost**
    • Duh et al (2009), review – generic substitution of antiepileptic drugs may increase overall cost, due to reduced seizure control
    • Gothe et al (2015), 8 publications (antiepileptics, immunosuppressives, atypical neuroleptics and anticoagulants):
      • The overall economic evidence is against generics. Generics were associated with higher cost of:
        • Concomitant medications
        • Outpatient services costs
        • Inpatient services costs
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• The bioequivalence limit by the FDA is 80-125% of the bioavailability of the originator drug
  • In USA, the limit is unchanged for Narrow Therapeutic Range (NTR) drugs
  • European guidelines provide a tightened acceptance interval of 90.00-111.11% for NTR drugs
  • In Australia, the limit does not apply to NTR drugs, e.g. no generic versions of digoxin or phenytoin, i.e. high generic consequences cost

• The general economic benefit of generics cannot be denied
  • Evidence based generic use - cost of disease research
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- In Qatar - local manufacturing is crucial, but...
  - Securing strategic trade partners other than few neighboring countries

<table>
<thead>
<tr>
<th>Level of Competition</th>
<th>Increase in Price</th>
<th>95% Confidence Interval</th>
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<tbody>
<tr>
<td>Highest (quadropoly)</td>
<td>-31.7%</td>
<td>-34.4% to -28.9%</td>
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<tr>
<td>Next-highest (duopoly)</td>
<td>-11.8%</td>
<td>-18.6% to -4.4%</td>
</tr>
<tr>
<td>Near monopoly</td>
<td>20.1%</td>
<td>5.5% to 36.6%</td>
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<tr>
<td>Monopoly</td>
<td>47.4%</td>
<td>25.4% to 73.2%</td>
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• Resources
  • Cheung W et al. Journal of Clinical Oncology 2017;34(15)
  • Gothe et al. Applied Health Economics and Health Policy 2015;13(1)
  • Rida N et al. Glob J Pharmaceu Sci 2017;1(4)
  • Tantash M. Journal of Generic Medicines 2012;9(1)
  • Dunne S et al. BMC Pharmacol Toxicol 2013;14(1)
  • Wouters O et al. The Milbank Quarterly 2017;95(3)
  • Dave C et al. Ann Intern Med 2017;167(3)