

القطاع الدوائي في قطر: يداً بيد في مواجهة الحصار

Medication Sector in Qatar: Hand in Hand Facing the Blockade



Economic Opportunity: Brand Drugs vs. Generic Drugs

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- 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



Economic Opportunity: *Brand Drugs vs. Generic Drugs*

- Originator (NDA) vs Generic (ANDA) review process requirements
- 20-90% cheaper generics

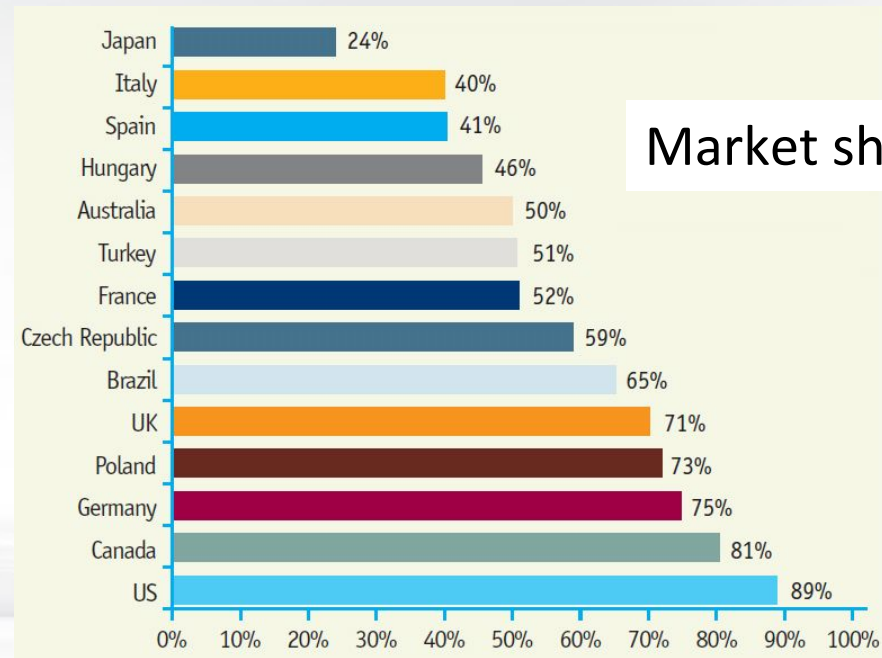
NDA Requirements	ANDA Requirements
1. Labelling	1. Labelling
2. Pharmacology/Toxicology	2. Pharmacology/Toxicology
3. Chemistry	3. Chemistry
4. Manufacturing	4. Manufacturing
5. Controls	5. Controls
6. Microbiology	6. Microbiology
7. Inspection	7. Inspection
8. Testing	8. Testing
9. Animal Studies	9. Bioequivalence
10. Clinical Studies	
11. Bioavailability	

- The generic drug industry is responsible for making more affordable and cost-saving medicines



Economic Opportunity: *Brand Drugs vs. Generic Drugs*

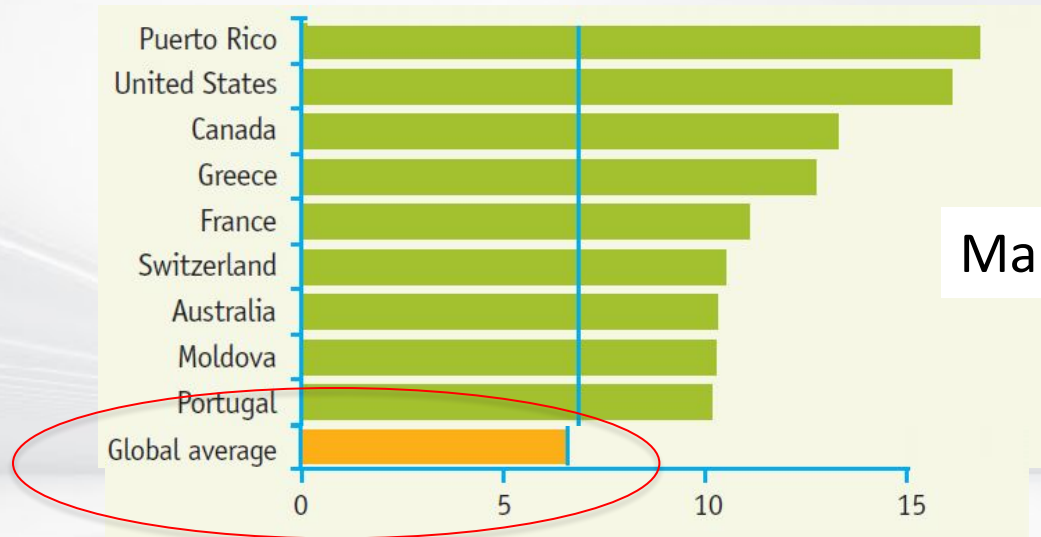
- USA, as example:
1980 – 17.3%
1990 – 32.0%
1997 – 43.0%
2009 – 63.5%
2016 – 89.0%



- Generics share in Qatar: 22%
- Average share in Middle East: ~28% (6% - 70%)



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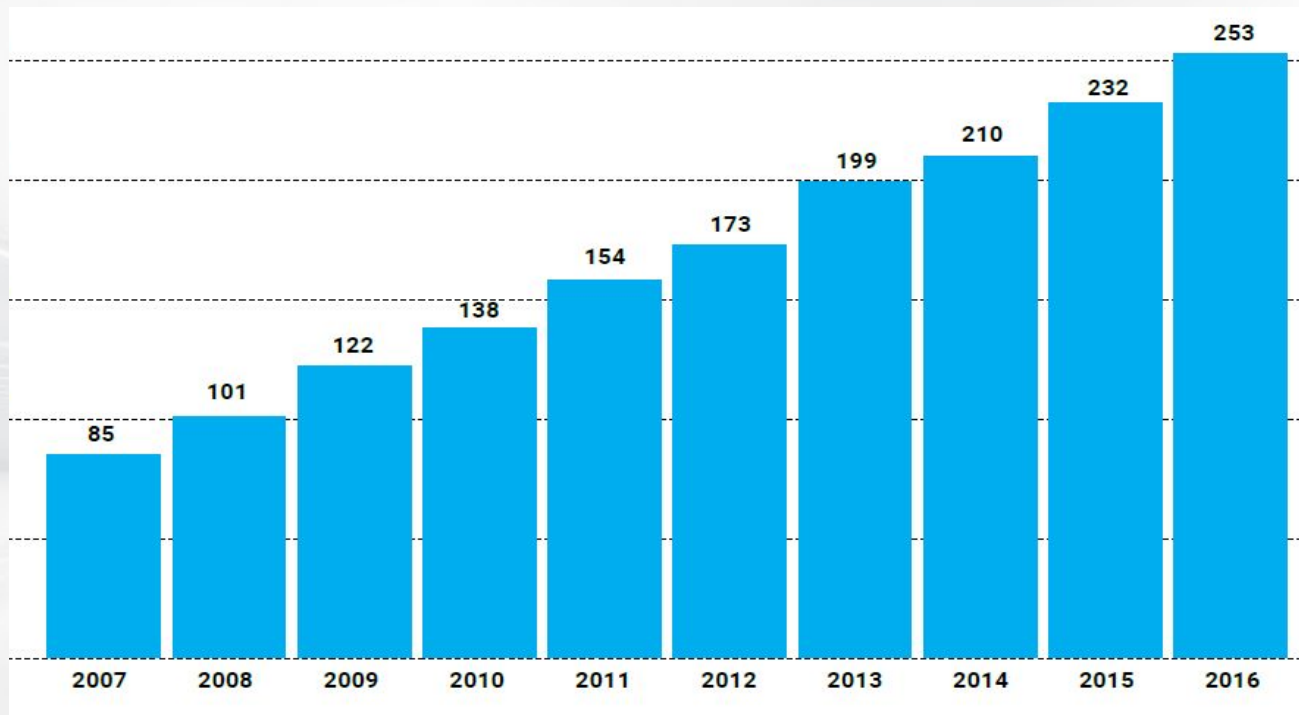


Market share (Value)



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- In USA, as example, in 2007-2016, \$1.7 trillion (\$5billion/week) were saved

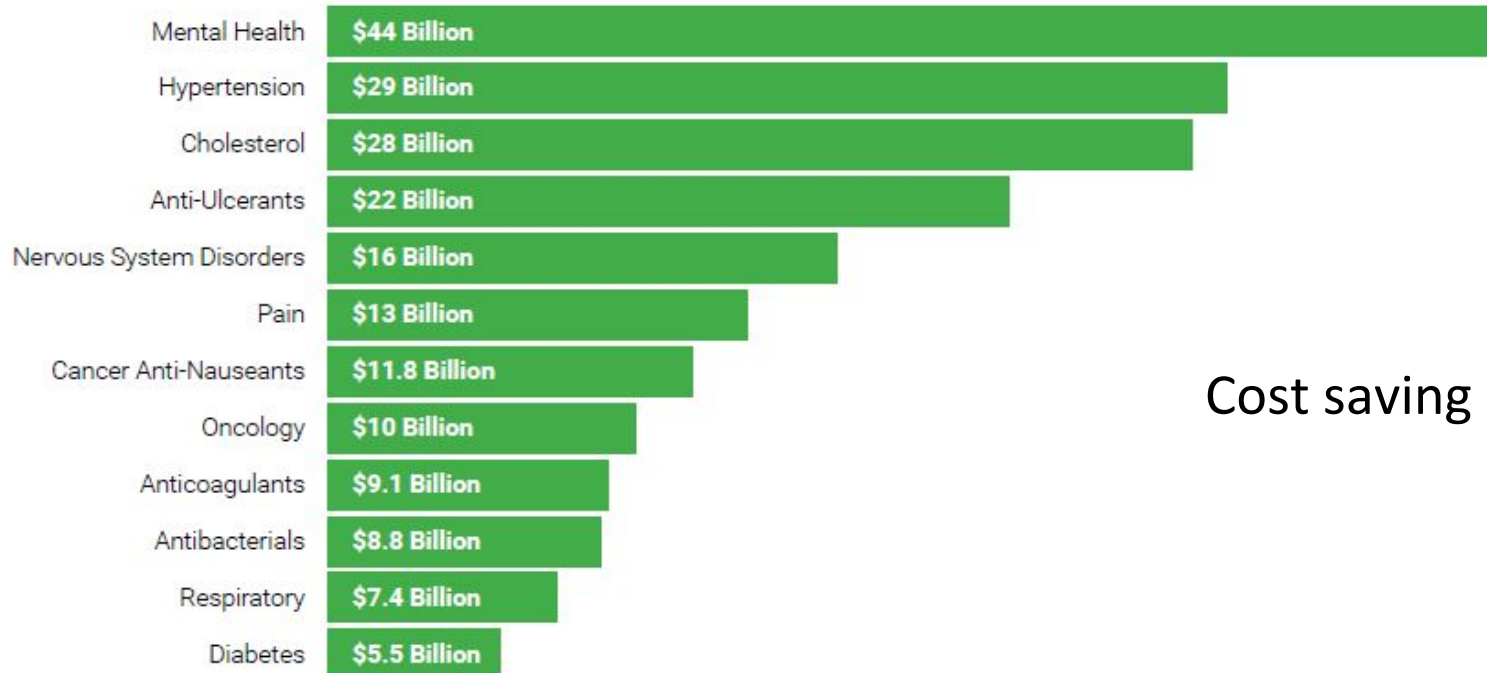


- In Canada, \$50,000 reduction in ICER per outcome





Economic Opportunity: *Brand Drugs vs. Generic Drugs*



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



Economic Opportunity: *Brand Drugs vs. Generic Drugs*

- In Qatar - local manufacturing is crucial, but...
 - Securing strategic trade partners other than few neighboring countries

Level of Competition	Increase in Price	95% Confidence Interval
Highest (quadropoly)	-31.7%	-34.4% to -28.9%
Next-highest (duopoly)	-11.8%	-18.6% to -4.4%
Near monopoly	20.1%	5.5% to 36.6%
Monopoly	47.4%	25.4% to 73.2%



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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)
- Association for Accessible Medicines. Generic Drug Access & Savings Report 2017.

<https://accessiblemeds.org/sites/default/files/2017-07/2017-AAM-Access-Savings-Report-2017-web2.pdf>

- Lieberman S et al. Brookings Institution. Sept 12, 2017.
www.brookings.edu
- 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)

