Jeff Watson
President, Apotex Global Generics

North American Market Trends

Not a harmonized market.

There are key differences in:

• Regulatory Systems
• Pricing
• Generic Utilization
• Supply Chains
• Market Size
North American Market Trends

Not a harmonized market

• Regulatory Systems:
  • Health Canada vs. FDA vs. COFEPRIS
  • Independent approval pathways, site licenses, inspections
  • IP systems and timing

• Pricing:
  • Canada: Provincially set generic pricing
  • US: open market negotiated
  • MX: open market negotiated for private sector, tender system for public sector
North American Market Trends

Not a harmonized market

- Generic Utilization:
  - Canada: 67.1%
  - US: 82.1%
  - Mexico: 84% (up from 50 percent in 2010 and includes branded generics)

- Total Market Size:
  - Canada: $18B USD (2014 CGPA)
  - US: $379B USD (2014 IMS)
North American Market Trends

Key Market Forces are Global Market Forces

- Tender system discussion in Canada
- Very public pricing discussion in the US

Pricing & Reimbursement

- FDA changes have impact on Global supply
- Improvements in time to approval in US

Consolidation

- Unprecedented consolidation in 2015
- $300B in industry consolidation
- Massive changes in wholesaler, retail and payer landscape

- Slowing of small molecule patent expiries
- This is off-set by opportunity in the biologics sector

North American Market Trends

Untested Biosimilars Market

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Biosimilars | U.S. | |
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**Granix was approved as a BLA, not a biosimilar
* Genotropin approved by the FDA under the 505(b)(2) pathway
Thank you.