

Legal and Regulatory Issues in the Russian Pharmaceutical Industry

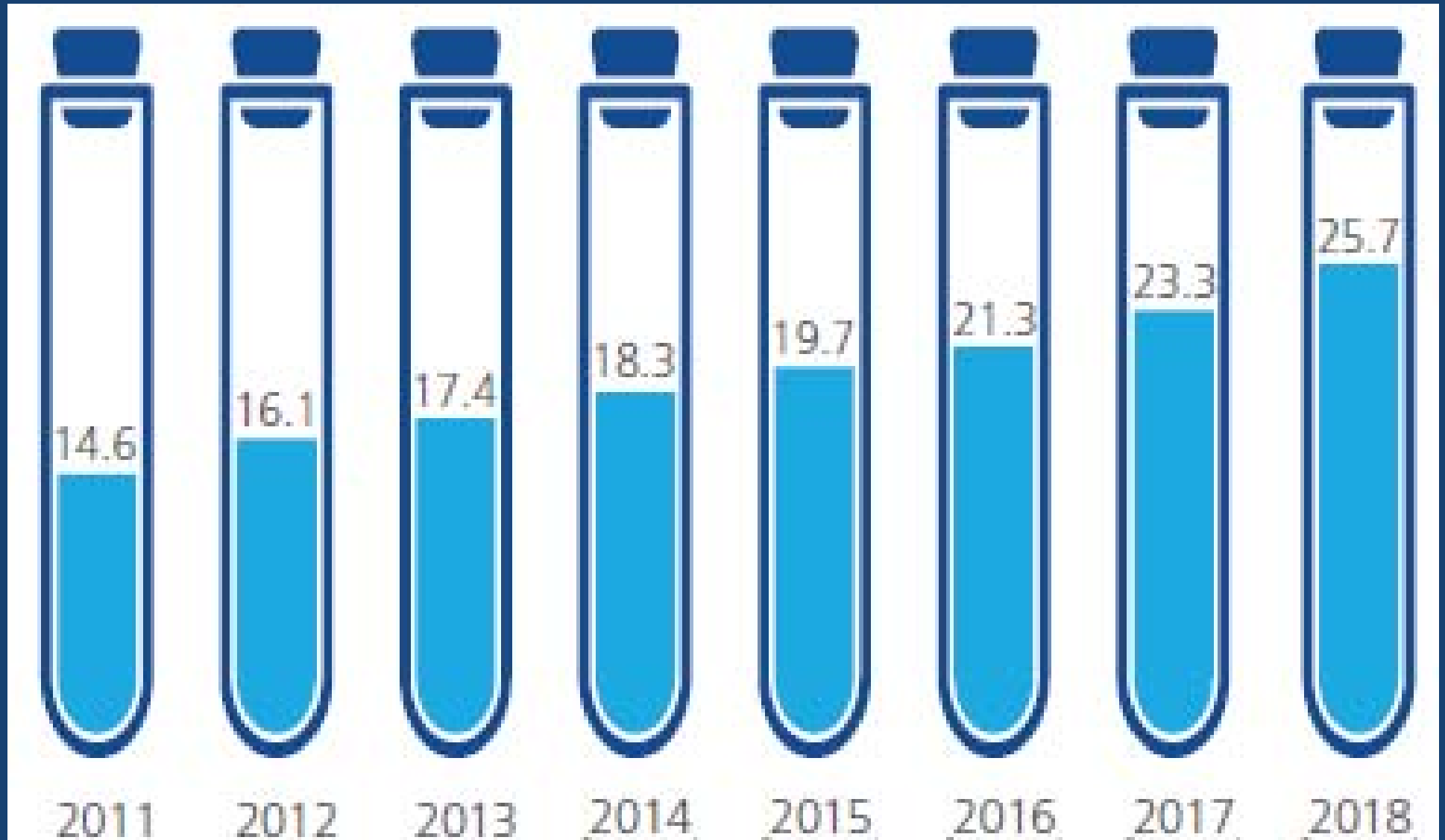
Bruce A. McDonald

BUCHANAN INGERSOLL & ROONEY PC

Philadelphia, PA

June 12, 2015

Russian Rx Industry 2011-2018 (Billion USD)



Russian Pharmaceutical Market Structure

- 57%: Commercial Segment
- 15%: Special Governmental Programs
- 15% : Natural Pharmaceuticals (Dietary Supplements)
- 13%: Hospital Purchases
- One Pharmacy Per 1,000 People
- Compare U.S. (4,500), UK (4,700)

Trends in Russian Pharmaceutical Industry

- Slowdown
- Increased Competition in Distribution & Retail Segments
- Decreased Profitability
- But, Still Growing
- 8th Largest Rx Market by 2017
- Driven by Commercial Segment

Russian Share of World Rx Market

	2008	2013	2017
1	USA	USA	USA
2	Japan	China	China
3	China	Japan	Japan
4	France	Germany	Brazil
5	Germany	France	Germany
6	Italy	Brazil	France
7	Canada	Italy	Italy
8	United Kingdom	United Kingdom	Russia
9	Spain	Canada	United Kingdom
10	Brazil	Spain	Canada
11	Mexico	Russia	India
12	Australia	India	Spain
13	Russia	Mexico	Mexico

Key U.S. Players

- Abbott Laboratories
- Abbvie
- Amgen Inc.
- Eli Lilly & Co.
- Innovative Pharma
- Johnson & Johnson
- MSD Pharmaceuticals
- Pfizer Inc.
- PhRMA

Key Factors in Development of Russian Pharmaceutical Industry

- Market Saturation
- Slower Growth
- But Still More Rapid than Europe or U.S.
- Localization

Legal / Regulatory Issues

- Localization
- 2013 Legislation
- Definition of “Local Manufacturer”
- Pricing of Essential Drugs
- State Procurement Procedures
- Approved Brands

Legal / Regulatory Developments 2013-2015

- Nov. 28, 2013: Resolution “On the Procedure for Approving the List of Medicines Ordered by Brand Names”
- Jan. 1, 2014: Law on State Procurement
- Jan. 1, 2014: Federal Law No. 61 “On the Circulation of Medicines”
- Strategy 2025
- Regulation by Ministry of Industry & Trade

Localization

- Russian Rx = 23% (Value), 56% (Volume)
- “Development of the Pharmaceutical and Medical Industry for 2013-2020”
- Share of Imported Medicines Decreasing

Legal & Regulatory Measures to Reduce Share of Imported Medicine

- State Procurement in Hospital Segment
- Government Financing
- Differentiated System of Preferences for State Procurement
 - Proposed by Ministry of Industry & Trade
 - Inducement to Localization
 - “Russian Producer” Status
 - Tax Relief
 - Indexation of Registered Prices for Locally Produced Essential Drugs

State Procurement

- Federal Law 44-Z, January 1, 2014
- Open Auctions / Tenders for Medicine
- List of Approved Brands to be Drawn Up
- Single Contract for Purchase of Multiple Rx Prohibited
- Limits Set on Purchase of Diversified Lots

Challenges to Russian Rx Industry

- Flawed Legal Regulation
- Corruption
- Lack of State Funding For Healthcare
- Support for Russian Manufacturers
- Economic Conditions / Sanctions

Legislative / Regulatory Issues

- Pricing Regulation
- List of Essential Drugs
- Tax Regulation / Transfer Pricing
- Definition of Local Manufacture
- Advertising Regulation
- Customs Union / WTO Harmonization
- IP Protection

Transfer Pricing

- Rules Effective January 1, 2012
- Documentation / Notification

Complaints by Western Companies

- Regulatory Data Protection
- Effective Patent Enforcement
- Government Pricing
- Government Procurement
- Local Clinical Trial Requirements
- Mislabeled Herbal Supplements

Regulatory Data Protection

- Aug. 22, 2012: WTO Accession
- “Law on Circulation of Medicines”
- 6-yr Regulatory Data Protection (RDP)
- Protects Against “Unfair Commercial Use”
- 3rd Party May Not Rely on Protected Data

Effective Patent Enforcement

- No Consideration of Patent Status in Approval of Generic Substitutes
- Difficulties in Securing Remedies and Injunctive Relief
- Absence of Preliminary Injunctions
- Unreasonable Court Delays
- Inability to File Infringement Suit Before Marketing of Follow-on Products Authorized

Mislabeled Herbal Supplements

- Products Labeled “Natural Ingredients”
- Actually Contain Patented Rx
- Failure of Regulation

THANK YOU

Bruce A. McDonald

BUCHANAN INGERSOLL & ROONEY PC

1700 K Street, N.W.

Washington, D.C. 20006

(202) 452-6052

bruce.mcdonald@bipc.com