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RUSSIA

Effects of government involvement in creating pharma strategy

MOLLY BOWMAN
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THOMSON REUTERS

AGENDA

- Overview of the market
- Government announcements
- API & finished dose manufacturing
- Foreign investment and partnerships
- Import regulations
- Innovation in Russia

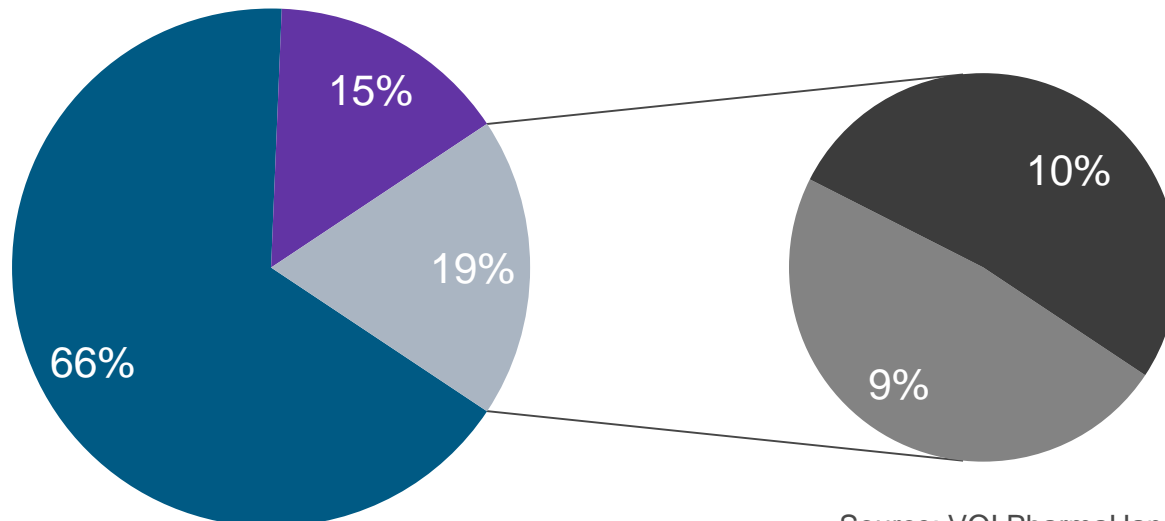
THE RUSSIAN MARKET

- CAGR around 13% during 2011-2013, market growth forecasts exceeding \$60bn by 2020
- Private healthcare taking off, growing prevalence of private physicians catering to the wealthy
- Average per capita consumption of medicines to quadruple in the next 10 years
- Foreign MNCs capture 80% of sales in the pharmaceutical market
- Generics hold 78% of the market volume and 20% market value
- 90% of substances used in pharmaceutical production are imported
- Marketing approval process is lengthy, unpredictable, and non-transparent
- Major problems that continue include corruption, bureaucracy, counterfeiting, poor data confidentiality

PHARMACEUTIAL MARKET SEGMENTS

- Privately paid out-patient pharmacies
 - Commercial segment, 2/3 of sales, fastest growing
- DLO (Additional Drug Supply Program)
 - Advantageous for foreign innovative drugs, imports account for 47% of volume
- Hospital

■ Private retail pharmacy ■ Hospital ■ DLO - Expensive diseases ■ DLO - all other



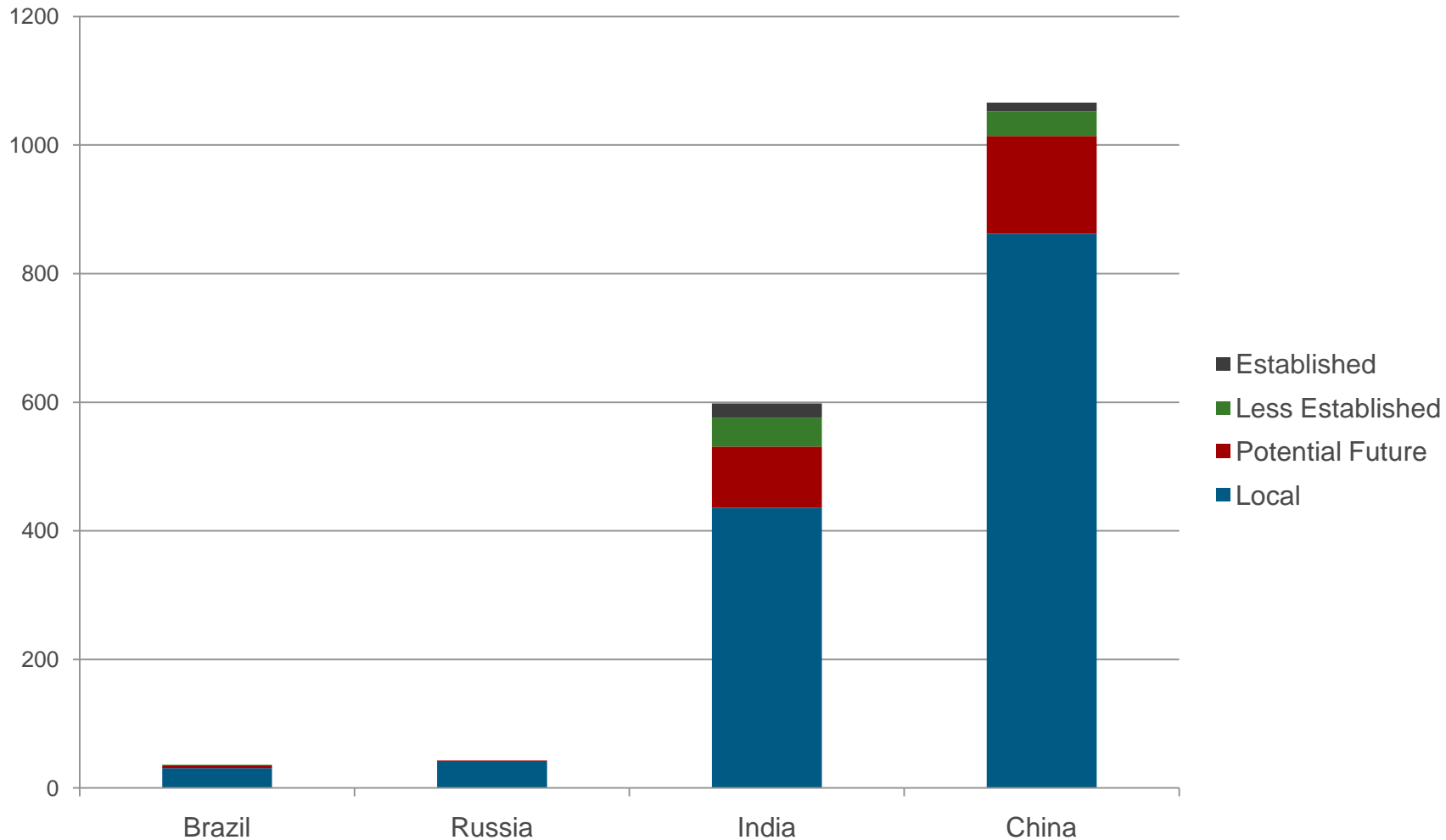
GOVERNMENT PLANS

- Promised \$3.9bn in federal funding to modernize
 - Increase domestic industry's share of total drug sales to 50% by 2020, from about 20% today
- Increase exports
- 57 essential medicines locally made
 - Oncology, HIV treatment, anesthetics, rare diseases
- New legislation
 - Improved transparency of drug registration process
 - No registration required for manufacturing ingredients
 - Defined timelines for application review
 - Aims to strengthen defenses against counterfeit products
 - New regulations on prices for 'essential medicine'
- Protectionist measures
 - Restrictions for companies that do not have a local presence

API MANUFACTURING

- Very limited local API manufacturing
 - <50 Russian-owned groups involved with API manufacturing
 - No manufacturing sites inspected by US FDA
- No local API manufacturing by regulated market players yet
 - ICN – Kursk owned by Millhouse Capital (UK)
 - 1 COS held by Biosintez Kombinat for fusidate sodium
- Gaps in technology
 - Everything except certain biologics

BRIC COUNTRIES - API MANUFACTURERS



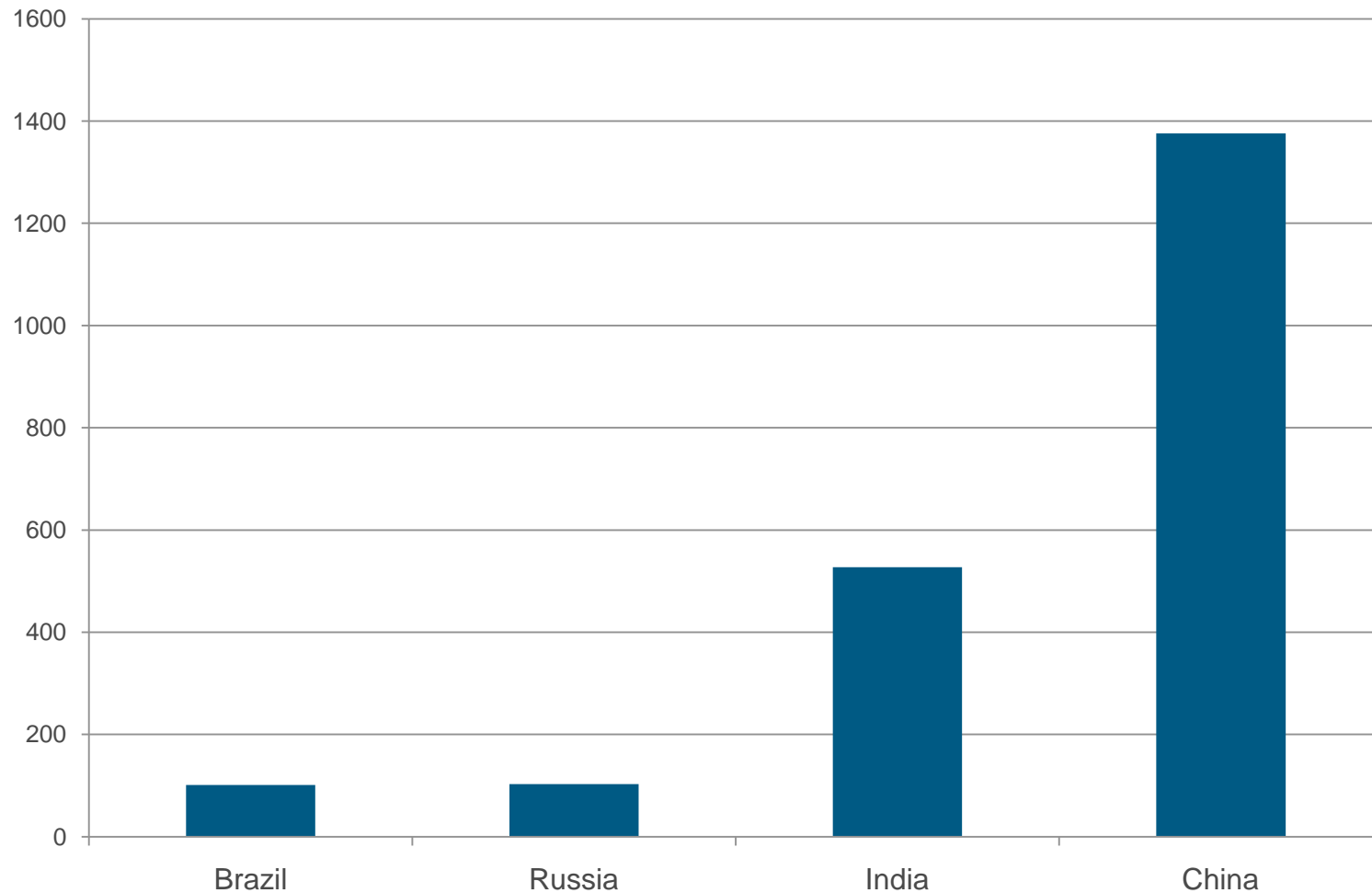
API IMPORTS INTO RUSSIA

API	From
arbidol	Italy
recombinant human insulin	France, Netherlands
choline alfoscerate	Italy, Switzerland, Hungary
cefazolin Sodium	China, Germany, Finland
cefotaxime	China, Germany, Korea, India, Canada
bicalutamide	Germany
vinpocetine	Spain, Switzerland, Croatia
afobazole	Italy
irinotecan HCl	China
doxorubicin HCl	Netherlands
ampicillin	Germany, India, Spain, China
paclitaxel	China, USA

FINISHED DOSE MANUFACTURING

- Strengthening local dose manufacturing
 - Up from <100 in 1990
- Very limited manufacturing of finished dose for export to regulated markets
 - 400 local manufacturers – 30 with GMP facilities
 - Nizhpharm allowed to make products for EU
- Companies based in Russia have launched finished dose in:
 - Argentina, Bangladesh, Brazil, Bulgaria, Colombia, Estonia, Hong Kong, Jordan, Latvia, Slovenia, Ukraine

BRIC – FINISHED DOSE MANUFACTURERS



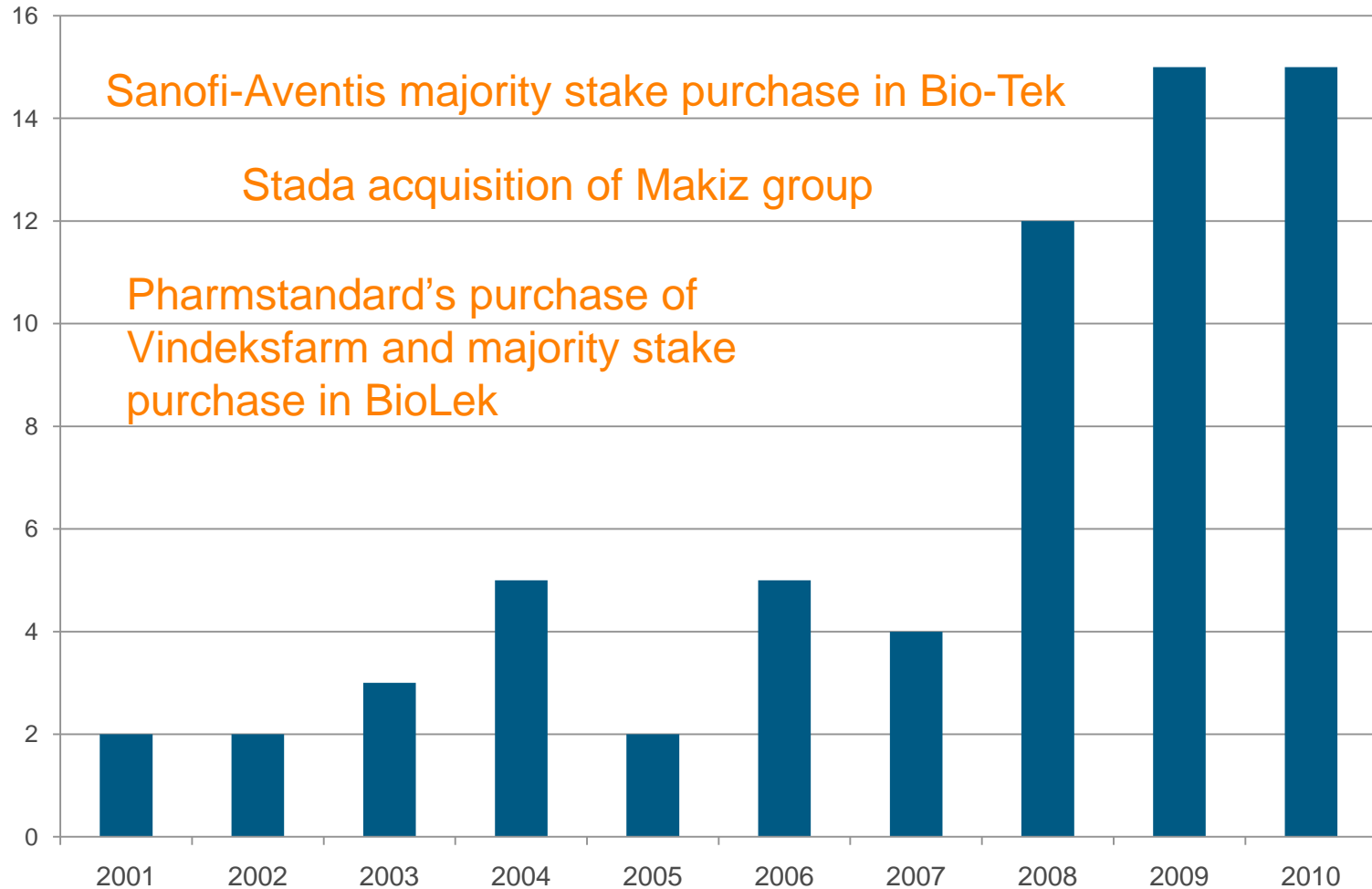
FOREIGN INVESTMENT

Company	Investments
Teva	Planning \$100M drug production plant
Novartis	\$500M pharmaceutical manufacturing facility
Nycomed	Investing \$93M API production plant
Sanofi – Aventis	Acquired insulin plant
Novo Nordisk	\$80-100M insulin facility
AstraZeneca	Planning \$150M drug production plant
Pfizer	Discussed building or buying established player
Servier	Built a \$80M production plant
Actavis	\$30M investment into Zio Zdorovje's manufacturing
Berlin-Chemie	Plant construction in Kaluga region
Dr Reddy's	Considering establishing production/R&D facility
Lupin	Considering \$50M plant/R&D center construction
Orion	In advance talks to acquire Russian firm, already has packaging projects
Ipsen	Receiving a pharmaceutical license, commercial activity Q1 2011

FOREIGN PARTNERSHIPS

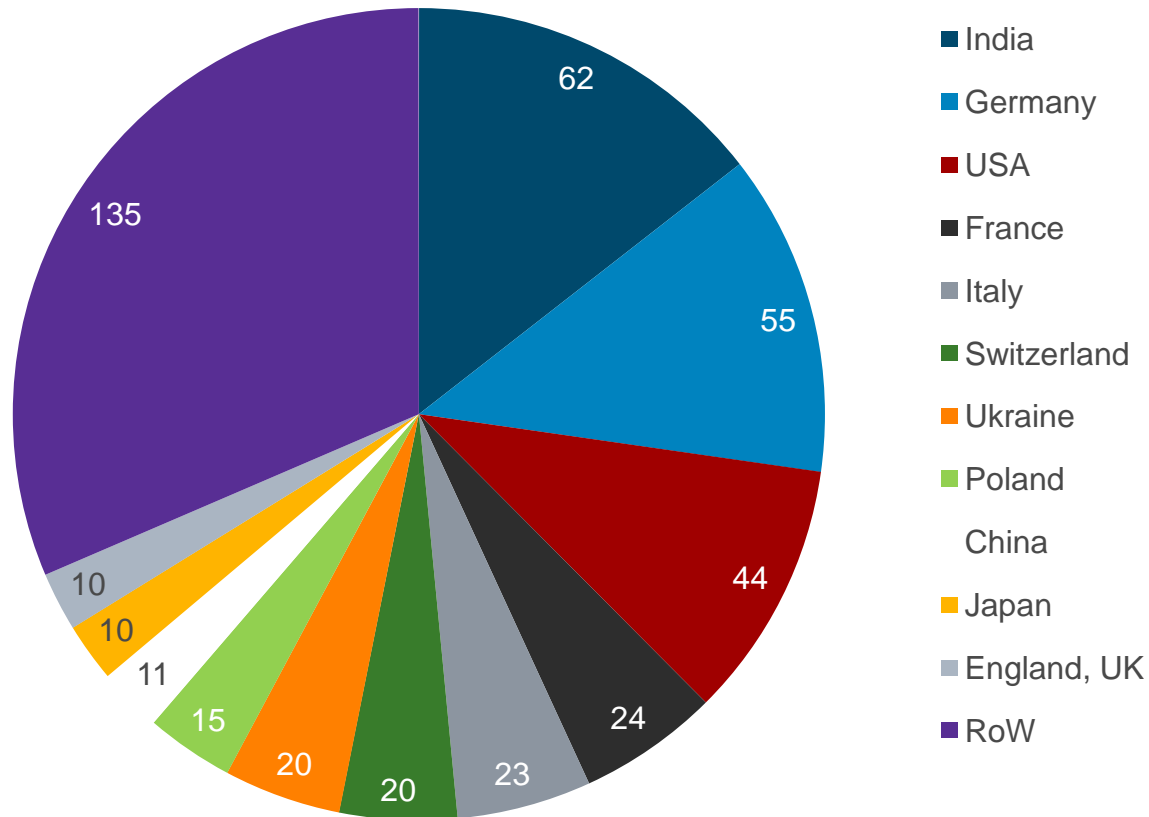
- Eli Lilly spending \$1.27bn to be founding member of Russia-US Research Foundation
- GSK & Binnopharm deal for vaccines
- Dr Reddy's & R-Pharm technology transfer
- Ranbaxy MoU with region for clinical trials
- Roche licensed drug candidates to Viriom
- Neuronascent signed SM screening agreement with Chemrar
- Jubilant and Kraspharma agreement on production & purchasing of raw materials
- Naprod Life Science and Farmasintez for production & purchasing of anticancer treatments

DEALS IN RUSSIA



FOREIGN PRESENCE

- Companies based outside of Russia with finished dose products on the Russian Market



FINISHED DOSE IN RUSSIA INDIAN COMPANIES

Manufacturer	Products
Orchid Chemicals	ciprofloxacin, metronidazole
Dr Reddy's	amlodipine, levofloxacin
Alembic	nimesulide, ceftriaxone
Aurobindo	ampicillin, cefazolin, ciprofloxacin
Cipla	fluconazole, clotrimazole
Ipca	acetaminophen, bromhexine, atenolol
Lupin	cefotaxime, diclofenac
Macleods	ofloxacin
Sun	carbamazepine, diazepam
Unichem	cetirizine, amlodipine
Rusan	bromhexine

FINISHED DOSE IN RUSSIA EUROPEAN COMPANIES

Manufacturer	Products
ACS Dobfar (Italy)	sulbactam sodium, cefazolin sodium, cefamandole nafate, cefuroxime
Fareva (France)	diclofenac
DSM (Netherlands)	nystatin, ampicillin, vitamins
Erregierre (Italy)	arbidol, afobazole
Farmabios (Italy)	budesonide
ICI (Italy)	ampicillin sodium, cefazolin sodium
Linnea (Switzerland)	vinpocetin
Pro Bio Sint (Italy)	adenosine triphosphate
Sandoz Industrial Products (Germany)	amoxicillin, clavulanate potassium, ceftriaxone, cefotaxime, erythromycin
Sifavitor (Italy)	cromolyn sodium
Swords Labs (BMS) (Ireland)	captopril

IMPORT REGULATIONS

- Import of drugs and pharmaceutical substances prohibited without first registering each product with Roszdravnadzor (RZD)
 - Registration procedure takes about 6-9 months
 - API in “transit” does not need to be registered
- Medicines Import Licenses granted by Ministry for Economic Development
- Since January 2007, system of Declaration of Conformity
 - Replaced prior system of mandatory certification
 - Applies to a particular consignment
 - Valid until the expiration date of the pharmaceuticals in the consignment

DUTIES & FEES

- Drug Registration
 - RZD fee for registration 2000 RUR (\$80)
 - Pre-registration “expertise fee” depends on the volume of expertise needed
 - API: ~\$5,000
 - Finished dose: ~\$19,000
 - Performed by division of RZD and Institute of Standardization and Control of Medicinal Products
- Import license – 0.05% of contract price
- Import Duties, VAT, and Custom Fees
 - Import duties: 5%, 10% or 15% depending on product
 - VAT: 0% or 10% depending on product
 - Custom fees: variable, including for custom legalization, custom escort, and storage

RUSSIAN INNOVATION

- Orphan drug research
 - Pharmsynthez received US FDA OD designation for cridanimod
- New use patents
 - azithromycin, fosinopril, tizanidine, bromazepam, isotretinoin
- Clinical trials
 - Domestic companies sponsoring 43% in 2010
 - Top domestic sponsors: Rafarma, Niopik, Pharm-sintez
 - Majority of trials focused on oncology

RUSSIAN INVESTMENT

- Pharmsynthez looking to purchase pharmaceutical producers in Europe, as well as in the US and Israel.
- Multiple companies looking for partnership opportunities outside of Russia
- Russian companies expanding facilities
 - Yunona building facility in Chelyabinsk region
 - Rusano & Pharmsynthez building new plant in Kapitolovo
- Multiple regions investing in healthcare modernization, improving hospitals and clinics

CONCLUSIONS

- Growing middle class with a growing demand for treatments of chronic diseases
- Poor infrastructure and a fragmented distribution network
- Large clinical trial population, physicians eager to participate in trials, low cost of clinical trials
- Russia continues to offer low-cost production, platform for launching into CIS, Eastern Europe
- Few local dose companies with cGMP experience, market likely continuing to be dominated by imports
- Poor enforcement of IP rights, counterfeiting, red tape, economic and political risks, language barriers
- Government investment and modernization will continue to be key priorities

THANK YOU

Molly Bowman
Manager, Small Molecule Research
Thomson Reuters

+1 207 871 9700 x13
molly.bowman@thomsonreuters.com