Focus on Central Asia and Eurasian Economic Union

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What countries are we talking about?

Central Asia
- Kazakhstan (17.4 million)
- Kyrgyzstan (5.7 million)
- Tajikistan (8.6 million)
- Turkmenistan (5.4 million)
- Uzbekistan (30.3 million)
- Total population 67.4 million

Eurasian Economic Union
- Russia (146.3 million)
- Kazakhstan (17.4 million)
- Belorus (9.5 million)
- Kyrgyzstan (5.7 million)
- Armenia (3.0 million)
- Total population 182.7 million

What’s in common?

- **Soviet Union heritage** in healthcare systems, mainly centralized and public; uptake of medical insurance system differs, but modest

- **Reimbursement of emergency care**, basic hospital and ambulatory care medical services, but reimbursement of essential medicines varies

- **Support to local producers**, mainly as preferences in state purchasing

- **Low enforcement of restriction** on prescription medicines sales over the counter

- **Considerable level of medicines counterfeiting**, and also smuggling

- **Regional integration** as CIS, and economic integration as EurAzEc, Single Economic Space and Customs Union, Eurasian Economic Union

Which differences matter?

- **Scope of state funding to public healthcare and extent of reimbursement**
  
  Reimbursement varies considerably from dominantly out-of-pocket markets of Tajikistan, Kyrgyzstan, Uzbekistan, and to comparatively high state funding in Russia and Kazakhstan

- **Regulatory and market access barriers to generics/biosimilar penetration**
  
  Ranking from higher barriers in Russia, then to Kazakhstan and less regulated and more accessible for generics/biosimilar/biocopies markets of Uzbekistan and Turkmenistan, down to Tajikistan

- **Level of development of local manufacturing and sufficient criteria for localization**

<table>
<thead>
<tr>
<th>Market size, bl USD, Trd, 2014 FY</th>
<th>Reimbursement vs out-of-pocket, %</th>
<th>Local production for internal market, %</th>
</tr>
</thead>
<tbody>
<tr>
<td>RUSSIA</td>
<td>KAZAKHSTAN</td>
<td>BELORUS</td>
</tr>
<tr>
<td>1.9</td>
<td>1</td>
<td>0.1</td>
</tr>
<tr>
<td>0%</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>1%</td>
<td>10%</td>
<td>20%</td>
</tr>
<tr>
<td>N/A</td>
<td>N/A</td>
<td>N/A</td>
</tr>
</tbody>
</table>

Drastic difference in patient access to efficacious, safe and modern treatment
**Eurasian Economic Union**

Currently five member states (RU, BE, KZ, KG, AR); free-trade agreement with Vietnam in May 2015, negotiations with Egypt and Thailand

- Based on key principles of free movement of goods, services, capital and labour within its borders (Unified Nomenclature of Goods)
- Common, coordinated, agreed policies in the economic sector and measures regulating foreign trade
- Common customs tariffs - no other customs duties, non-tariff regulatory, safeguard, anti-damping, countervailing measures to mutual trade

[http://www.eaeunion.org/?lang=en#about](http://www.eaeunion.org/?lang=en#about)

**Common market of medicines**

**ESTABLISHING THE COMMON MARKET OF MEDICINES**, to start function from January 2016 (transition period provided)

<table>
<thead>
<tr>
<th>Supranational level</th>
<th>National level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Eurasian Economic Commission</td>
<td>National Authorities</td>
</tr>
<tr>
<td>Expert Committees</td>
<td></td>
</tr>
</tbody>
</table>

**Harmonization and unification of rules on circulation of medicines:**
- GxP practices (GMP, GCP, GPvP, etc)
- registration rules and requirements for quality, effectiveness and safety
- common MA template (unlimited validity period)
- joint pharmaceutical audits and reports

**Common Registries of:**
- Medicines and medical devices,
- Pharm Auditors,
- QPs

**Licensing for**
- manufacturing
- distribution, etc

**Registration (approval) of medicines and medical devices**
- issuance of MA
- further Mutual Recognition

**Pharmacovigilance system**
- mandatory exchange of data

*Treaty on Eurasian Economic Union, Section VII, Art 30,100. https://docs.eaeunion.org*
Common market of medicines

Priorities of National Economy
Pharmaceutical Industry
Kazakhstan’s priority is to create environment for the import substitution of pharmaceutical and medical products based on modern technologies complying with international GMP standards.

Priorities of National Economy
Medical Technologies and Pharmaceuticals
The key goal is to produce most of medicines and medical devices in Russia, develop and produce innovative pharmaceuticals, as well as get access for Russian manufacturers to new markets.

Priorities of National Economy
Medical Technologies and Pharmaceuticals
Launching pharmaceuticals production in Belarus provides a duty-free access to the large and dynamically growing market of all three of the SES Member-States (Russia, Belarus and Kazakhstan).

http://www.eaeunion.org/?lang=en#about-countries

What’s important for generics and biosimilar?

Equal access to state purchasing in all member states may lead to discrepancies with regards to market penetration and referent pricing

Number of MAs of Euroasian EU producers in respective countries and split

<table>
<thead>
<tr>
<th>Country</th>
<th>MAs</th>
<th>Kazakhstan</th>
<th>Armenia</th>
<th>Belarus</th>
<th>Russia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Russia</td>
<td>14 378 MAs</td>
<td>43%</td>
<td>0%</td>
<td>11%</td>
<td>46%</td>
</tr>
<tr>
<td>Kazakhstan</td>
<td>1 724 MAs</td>
<td>1%</td>
<td>33%</td>
<td>17%</td>
<td>50%</td>
</tr>
<tr>
<td>Armenia</td>
<td>836 MAs</td>
<td>1%</td>
<td>0%</td>
<td>0%</td>
<td>97%</td>
</tr>
</tbody>
</table>

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THANK YOU