Price regulation models in Turkey and the Russian Federation

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London School of Economics
NPPA Seminar, New Delhi, April 2008
## The context: Why Turkey and Russia?

<table>
<thead>
<tr>
<th>Attribute</th>
<th>Turkey</th>
<th>Russia</th>
</tr>
</thead>
<tbody>
<tr>
<td>Implementing Health Reform</td>
<td>Yes (branded)</td>
<td>Yes (branded)</td>
</tr>
<tr>
<td>Market predominantly generic</td>
<td>Yes (branded)</td>
<td>Yes (branded)</td>
</tr>
<tr>
<td>Inequity in access to essential medicines</td>
<td>Can be significant</td>
<td>Extensive/most</td>
</tr>
<tr>
<td>Significant OOP expenditures</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Drug sector reform</td>
<td>Yes (expand cover)</td>
<td>Yes (introduce cover)</td>
</tr>
<tr>
<td>Lack of Rx drug coverage</td>
<td>No (in principle)</td>
<td>Yes</td>
</tr>
</tbody>
</table>
Relevance to India?

1. Pricing methodology
2. Dealing with in-patent vs. off-patent medicines
3. Generic pricing and generic policy
4. Tendering and affordable pricing
5. Role of the distribution chain
6. Dealing with providers
Pharmaceutical Policy in Turkey: improving coverage and efficiency?
Key features: a snapshot

- Incomplete health insurance cover; unified in 2009
- Significant OOP component
- Significant indigent population (11 million or 15% of total population of 72 million)
- Inequitable access to care and drugs
- Significant informal payments
- Hospital charges form part of physician salary through revolving funds
- Branded generics market; unbranded generics are unknown in Turkey
- 1388 active ingredients and 3667 products with different forms (about 7000) as of May 2005
Out-patient drug expenditure 2005

(€ per capita)
Market Penetration of Generics

Volume: [Bars for each country showing volume penetration]
Value: [Bars for each country showing value penetration]

Countries: USA, Germany, UK, Netherlands, Denmark, Turkey
## Pricing criteria for in-patent products in selected OECD countries and Turkey

<table>
<thead>
<tr>
<th>Feature</th>
<th>UK</th>
<th>GER</th>
<th>FRA</th>
<th>ITA</th>
<th>SPA</th>
<th>DEN</th>
<th>POL</th>
<th>NET</th>
<th>TUR</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical value</td>
<td>?</td>
<td></td>
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<td>?</td>
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<tr>
<td>Comparator prices</td>
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<td>?</td>
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<tr>
<td>Sales volumes</td>
<td>?</td>
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<td></td>
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</tr>
<tr>
<td>Price freedom</td>
<td>?</td>
<td>?</td>
<td>?</td>
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<td>?</td>
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</tr>
</tbody>
</table>

- Pricing process usually kept separate from reimbursement process
- Explicit rule of international benchmarking applies: lowest of Greece, Italy, France, Spain, Portugal
- Evidence-based pricing over the medium-term
- Cost-effectiveness submissions for new products
Prices of generics are often controlled in various ways.

In Turkey, generic prices are capped (-20% of originator) and a reference pricing system applies in principle for reimbursement (lowest + 30% markup).

Sector dominated by branded rather than unbranded generics.

Doubtful that generic pricing policy leads to cost savings in Turkey.

<table>
<thead>
<tr>
<th>Feature</th>
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<th>DEN</th>
<th>POL</th>
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<th>TUR</th>
</tr>
</thead>
</table>
### Criteria for pharmaceutical reimbursement

<table>
<thead>
<tr>
<th>Criteria</th>
<th>UK</th>
<th>GER</th>
<th>FRA</th>
<th>SPA</th>
<th>NET</th>
<th>POL</th>
<th>ITA</th>
<th>CAN</th>
<th>TUR</th>
</tr>
</thead>
</table>

- Negotiation on the basis of multiple criteria
- Policies differ depending on national priorities
- Increased coverage, epidemiological patterns and current lifestyles in Turkey may place strain on available resources and as a result reimbursement policy needs to be streamlined using EBM principles and economic criteria over the medium term
Official margins are regressive as per current international practice.
Pharmacists allowed to substitute, in practice they rarely do, or do so for a more expensive medication.
Effectiveness of regressive margins as tools for “efficient” or cost effective dispensing is doubtful due to (significant and allowable) discounts.
Distribution chain may benefit disproportionately.

<table>
<thead>
<tr>
<th>Ex-Manufacturer’s Price (in NTL)</th>
<th>Wholesaler (%)</th>
<th>Pharmacy (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>The part = 10</td>
<td>9</td>
<td>25</td>
</tr>
<tr>
<td>The part between 10-50</td>
<td>8</td>
<td>24</td>
</tr>
<tr>
<td>The part between 50-100</td>
<td>7</td>
<td>23</td>
</tr>
<tr>
<td>The part between 100-200</td>
<td>4</td>
<td>16</td>
</tr>
<tr>
<td>The part &gt;200</td>
<td>2</td>
<td>10</td>
</tr>
</tbody>
</table>
## Formal and informal out-of-pocket expenses in the Turkish health care system

<table>
<thead>
<tr>
<th>Purpose</th>
<th>Public Providers</th>
<th>Private Providers</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Formal</td>
<td>Informal</td>
<td>Formal</td>
</tr>
<tr>
<td>Donation</td>
<td>-</td>
<td>11.1</td>
<td>-</td>
</tr>
<tr>
<td>Physicians' medical services</td>
<td>9.2</td>
<td>2.3</td>
<td>29.8</td>
</tr>
<tr>
<td>Physicians' surgical services</td>
<td>8.2</td>
<td>23.5</td>
<td>-</td>
</tr>
<tr>
<td>Drugs</td>
<td>70.3</td>
<td>50.5</td>
<td>49.7</td>
</tr>
<tr>
<td>Nurses' /other staff's care</td>
<td>-</td>
<td>1.5</td>
<td>-</td>
</tr>
<tr>
<td>Laboratory/ imaging tests</td>
<td>8.1</td>
<td>-</td>
<td>12.2</td>
</tr>
<tr>
<td>Other services</td>
<td>4.0</td>
<td>11.1</td>
<td>8.3</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td><strong>100.0</strong></td>
<td><strong>100.0</strong></td>
<td><strong>100.0</strong></td>
</tr>
</tbody>
</table>

The Proxy demand

- Physicians always prescribe by brandname; although pharmacists can substitute for a (theoretically cheaper) generic, the entire system may not necessarily create any savings worthwhile mentioning.
- There is a Multi-tier system with physicians contracted, but also practicing privately.
- Enforcement of available clinical guidelines by clinicians remains non-existent.
- At the other end of the spectrum, an increase in “productivity” is thought to occur through physicians’ supplementary payments (Physician Rx behaviour in hospitals is explicitly linked with the size of the hospital revolving fund, from which physicians draw a significant proportion of their salary).
Lessons from Turkey

- Formal use of international price benchmarking with identified basket of countries
- Value of new products examined with CE submissions
- Fixed distribution margins as % of ex-M price; margins are regressive
- Discounts to wholesalers and retailers from off-patent segment rampant w/out ability for health insurance to claw-back
- System under-funding promotes informal payments and encourages patients to by-pass formal channels
- Non-transparency of criteria used to admit new medicines to reimbursement
- Little chance for a generic policy to work as physicians Rx brand and pharmacists dispense brand
- Little is done to promote rational drug use, monitor physician Rx patterns or audit physicians
- Very little (if at all) use of IT in decision-making
The Russian Federation: Improving access for the sickest part of the population and shaping the environment for a leading role in R&D in years to come
## Russia: Healthcare macroeconomics

|-------------|----------------------|----------------------------------|-----------------------------|-----------------------|----------------------------------------------------|-------------------------------------------------------------|--------------------------------------------------------------------------------|-------------------------------------------------|

Range in analyzed countries: From 7.5% in Finland to 10.9% in Germany, Average: 9%

Range in analyzed countries: From 30% in Greece to 11% in the UK, Average: 15%

Range in analyzed countries: From 204 in Canada to 360 in Finland, Average: 285

Countries analyzed: CANADA, FINLAND, FRANCE, GERMANY, GREECE, ITALY, PORTUGAL, SPAIN, and UK
Some stylised facts

1. National priority projects
   - Health: $7.74 bn (incl. $1.4 bn pharmaceuticals)
   - Eucation: $2.09bn
   - Housing: $2.22bn

2. Health insurance
   - Basic cover; insurance fund operating at central and regional level
   - No Rx drug cover until 2005
   - 2005: introduction of DLO system for “veterans and invalids” with immediate cash injection of $1.4 bn
   - Both hospital and outpatient
   - Working population still not covered for Rx medicines; separate insurance scheme under preparation
Federal reimbursement program
Development stages of further improvements

<table>
<thead>
<tr>
<th>STAGES</th>
<th>2007</th>
<th>2008</th>
<th>2009</th>
<th>2010</th>
</tr>
</thead>
<tbody>
<tr>
<td>I</td>
<td>DLO - Federal beneficiaries</td>
<td>(veterans, invalids (1-2 groups) etc.)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>II</td>
<td>Regional beneficiaries</td>
<td>(pregnant women, mothers &amp; children &lt; 3 y.o., invalids (3rd group))</td>
<td></td>
<td></td>
</tr>
<tr>
<td>III</td>
<td>Co-payment</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>IV</td>
<td>Working citizens</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Pensioners</td>
<td></td>
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</tbody>
</table>

Ministry of Healthcare and Social Development, 2007
Russian pharmaceutical market structure in 2004-2005 (in retail prices)

Source: Retail Audit of Russian Pharmaceutical Market by DSM Group, QMS meets the requirements of ISO 9001:2000
Drugs consumption in Russia in comparison to other European countries

*Drugs consumption in Russia and in Moscow – in 2005, according to DSM Group and Goskomstat data
Drugs consumption in other countries – in 2004

Sources:
European Association of Pharmaceutical Full-line Wholesalers, IMS Health,
Retail audit of Russian pharmaceutical market by DSM Group, Goskomstat
1. In-patent medicines

- No explicit price regulation
- A version of free pricing s.t. submission of a price with dossier for MA
- Federal regulator responsible for MA and price registration
- In practice submitted price needs to be in line with EU market leaders
- Therefore, an informal international price benchmarking in place with a notional basket of countries
Top 50 Sales G10
Index* Ex-Factory Prices

*NOTE Index: Weighted Average Price G5 Europe is 100

USA: 250
Japan: 180
Mexico: 150
Canada: 110
Australia: 80
EU-G5: 85-115

Russia: International Reference Pricing
Russia: 105

Index* Ex-Factory Prices
0 50 100 150 200 250 300
USA JAPAN FRANCE GERMANY ITALY SPAIN UK AUSTRALIA CANADA MEXICO RUSSIA

1-10 ($37442 MM) 1-20 ($57491 MM) 1-30 ($71455 MM) 1-40 ($80403 MM) 1-50 ($84170 MM)
2. Off-patent medicines

- No regulation
- Discussion about reference pricing at molecule level as a means of cost control
- Prices in most part slightly lower than in-patent originators
- Compulsory INN prescribing since January 2007
- FFOMI enforces INN dispensing
- Strong information systems at central and regional levels
- There may be delays in dispensing a generic because of shortages
Drug distribution

- Wholesale distribution a geographical monopoly
- Licenses awarded to wholesalers, 1 license per geographical region
- Wholesalers required to set up IT system with all pharmacies and collect all prescriptions on behalf of health insurance
- Vertical integration – federal operators develop their own production facilities focused on reimbursement (Protek, SIA, Biotec) and pharmacy chains (Protek, Biotec)
- 15% “visible” margin and additional 25-40% “invisible” margin
- Visible margin lower (10%) for tender products
Before discounting, wholesalers make up 15% of the overall drug price, while pharmacy mark-up makes up 4%. These figures vary widely from other countries.
The biggest MS (%) of in-patient drugs is in State Reimbursement Segment (25%). As the Government officials declare Federal Reimbursement Program’s aim is to provide different categories of people by high effective pharmaceuticals.

* “Innovative” drugs: INN is under patent protection.

Market share of innovative drugs in total market in 2005 is 12.8% (incl. ethical pharmaceuticals lost patent protection).

(incl. ethical pharmaceuticals lost patent protection)
Shifts in consumption lead to decrease of the cheapest traditional pharmaceuticals sales value; Pharmaceuticals with the price $1 - $5 are decreasing their value terms, but in volume they are growing. Thus the generics are used more frequently but their price is reducing due to great competition in this segment.

Pharmexpert's estimations, Rozdravnadzor.
Lessons from the Russian Federation

1. No formal price control for in-patent medicines, but a notional basket of countries and international benchmarking
2. As generic market is predominantly branded no price regulation, but obligation to Rx INN
3. System underwrites cost for the weakest segment of society since 2005
4. Wholesaler enforces policy on behalf of health insurance
5. Information is collected and analysed by health insurance
6. Since Rx drug cover was introduced, uptake of expensive treatments increased, esp. for cancer, mental and cardiovascular disease
7. Tendering of expensive products (oncology, HIV, blood products) in order to reduce wholesaler margins
Overall

- Insurance cover increases access to and availability of needed treatments (RU)
- International price benchmarking for in-patent products for simplicity (TR, RU)
- Variability in generic pricing
  - (Relative) price freedom for generics (RU)
  - Price control with some clustering to ensure price differences not vast (TR)
- Discounting practices rampant with little ability (or willingness) to claw-back excess discount (TR, RU)
- INN Rx can help contain cost (RU) but only if
  - Originator-generic price differential is significant
  - There is enforcement of the policy
- Use of IT to determine utilisation, over- and under-prescribing (RU)