

# Impact of pharmacoeconomics on pricing in Russia: experience and perspective

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# How are expenses of medications paid in Russia (ambulatory)?

- Provision with essential drugs (ONLS, former DLO) – 2 mln. of people (1.4% of population of Russia)
- Regional benefit – 8 mln. of people (5.6% of population of Russia)
- “7 nosologies” – 76.000 of people (0.05% of population of Russia)
- Purchasing of drugs by population

# How are prices on medications regulated?

- Registration of marginal price for vital and essential medications
- Fixation of marginal wholesale and retail bidding to sale prices on medications from Vital and Essential Drug List
- Pricing of medication, not included in Vital and Essential Drug List (previously – in DLO) is not regulated absolutely

# Pricing in pharmacy (free sale)

- Custom price
- Custom duty (11%) + value added tax (VAT, 10%)
- Price markup of distributor (not less than 2 distributors) (practically 30% from each one)\* + VAT (10%)
- Price markup of pharmacy (up to 30%) + VAT (10%)

\* Despite of data of Stature on State Regulation of Prices, approved by Decree of Government of Russian Federation, 9, November, 2001, # 782 (III.16): the sum of wholesale markups of all wholesale organizations, taking part in selling of medication on the territory of region of Russian Federation must not exceed relevant marginal wholesale markup, proved by executive legislative body of this region of Russian Federation

# Forming of wholesale and retail markups

- It can be fixed by executive legislative body of regions of Russian Federation only for the medications from the Vital and Essential Drug List
- It is regulated by Decree of Government of RF from 7, March, 1995 #239 and Decree of Government of RF from 9, November, 2001 #782
- Prices and assortment of production in hospitals and pharmacies are controlled by Roszdravnadzor selectively for 130 drugs (Order of Ministry of Public Health and Social Development of RF from 27, May, 2009 #277n )

# In practice, markups are overpriced

- Rostov Region\*: retail markups are 25-45% despite of limited 23%; wholesale markups are 27.5-68.6% despite of limited 10%.
- Kaluga Region\*\*: retail markups are 34-60%, at the same time fixed one is 30%
- Izhevsk\*\*\*: retail markups are 40%, fixed ones – 35%
- Nizhniy Novgorod\*\*\*\*: wholesale markups are 17-25%, fixed ones –15%

\* [http://www.donland.ru/rst/Inform\\_organizatsijam/2065.pdf](http://www.donland.ru/rst/Inform_organizatsijam/2065.pdf)

\*\* <http://www.regnum.ru/news/fd-central/kaluga/medicine/1195636.html>

\*\*\* <http://www.kprf-udm.ru/news-archive/2586-lekarstva>

# Total markups for the sale

- 328% - Detralex (Servier)
- 196% - Actovegin (Nycomed)
- 108% - Essentiale forte (Sanofi Aventis)
- 122% - Linex (Lek)
- 45% - Viagra (Pfizer)

# Forming of price

- ONLS – tender
- “7 nosologies” - tender
- Regional benefit - tender
- Custom are performed according Federal Law #94
- Conditions: the lowest price of drugs, in one region – the presence of data on bioequivalence for generics

# Chaotic energies on the regulation of pricing

- Decree of President of RF, 28, February, 1995 #221
- Regulation of Government of RF, 07, May, 1995 #239
- Regulation of Government of RF, 9, November, 2001, #782
- Order of Ministry of Public Health and Social Development of RF, 19, October, 2004 #165
- Order of Ministry of Public Health and Social Development of RF, 31, December, 2006 #907
- Order of Ministry of Public Health and Social Development of RF, 27, May, 2009 #277n
- Regulation of Government of RF, 8, August, 2009 #654

# Registration of prices

- Mandatory registration of sale price of producer on medication from Vital and Essential Drug List (for the present time – only 25% of drugs have registered price)
- Registered prices are reflected in State Register of Drug Prices (24 issue) \*
- Registered prices sometimes are higher than real sale prices, prices are not newly registered for several years

# Comparative evaluation of prices of drugs, rub.

<b>IUN</b>	<b>Registered price according to LVSD, rubles</b>	<b>Price in pharmacy (Moscow), ruble</b>
<b>Captopril Tab.25 mg #20</b>	<b>6,00 - 26,37</b>	<b>4,22 39,00 (Capoten 57,00 - 160,00)</b>
<b>Enalapril Tab.2.5 mg #20</b>	<b>3,89 - 47,99</b>	<b>4,09 - 125,10</b>
<b>Atenolol Tab.50 mg #30</b>	<b>16,50 - 48,00</b>	<b>5,10 - 50,00</b>
<b>Formoterol Caps.pulv. For inject. 12 µg #30</b>	<b>825,35</b>	<b>611,50 - 1098,48</b>
<b>Amoxicillin Caps.250 mg #20</b>	<b>46,25</b>	<b>12,14 - 45,00</b>
<b>Azithromycin Caps.250 mg #6</b>	<b>78,53 - 220,00</b>	<b>79,50 - 590</b>
<b>Co0trimoxazole Tabl.480 mg #20</b>	<b>10, 20 39,91</b>	<b>7,00 - 25,90</b>

# At the present times

- Present mechanisms of price growth containment are ineffective – during 8 months of 2009 year the medium price of drug raised on 35%, and sales volume decreased on 7.7% in pharmacy\*
- System of prices is not stable, it is liable to significant influence of rates of exchange
- Pharmacoeconomics is not used in registration of price, the system of referent pricing is absent
- Reimbursement of drugs for only 10% of population of Russia and lack of regulation of pricing significantly decreases of access to drugs for people

# New initiatives

## of Government of RF\*

Who can develop it and  
which will they be?

- 2 methods are in development: determination of fixed sales prices of producer for medicines from Vital and Essential Drug List, method of definition of wholesale and retail markups to Vital and Essential Drug List
- Monthly monitoring of prices in pharmacies by Roszdravnadzor
- Re-registration of prices of all medicines from Vital and Essential Drug List up to 1, March, 2010 according new method
- New mechanisms of control over innovations are developed

\* Decree 8, August, 2009 #654 "On perfection of state regulation of prices of vital and sufficient drugs"

# New initiatives of Government of RF (2)

- Substantiation during registration of price of Russian producer must include a data on price of drug with information of IUN and form of production in Russia
- Substantiation during registration of price of foreign producer must include reference data on price of drug in country-producer
- Executive legislative body of regions of Russia can fix wholesale and retail markups to all drugs, but not only to ones included in Vital and Essential Drug List