

# Medicines lists as policy instruments in Tatarstan and Russian Federation in the 21st century



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## Abstract

**Problem statement:** Pharmaceutical situation in Russia changed dramatically since early 90th. The number of registered medicines kept increasing with over 19000 registered products by 2010. The new time required re-evaluation of strategic approaches to health. Governmental funds have been allocated and governmental projects of Supplementary medicines provision for selected patient categories and project "Health" have been initiated with introduction of corresponding medicines lists.

**Objectives:** To compare medicine lists, effective in Tatarstan and Russia, with WHO Model List of Essential Medicines (EML) and identify problems in medicine selection. Since the latest Russian Essential Medicines List (REML) was developed with the sole purpose of regulating medicine prices, the comparative analysis was intended to assess if this policy could contribute to better access and use of medicines.

**Design:** Descriptive study

**Setting:** The study was conducted at the national and provincial level, public sector.

**Outcome measures:** We analyzed increments in numbers on the lists as compared to WHO EML from 2000. We compared medicines lists effective in Tatarstan in 2009 with the 16th WHO Model List of Essential Medicines, WHO EML: Russian Essential Medicines List, REML (2009), Russian Supplementary Medicines Lists, RSML (2008), Tatarstan Supplementary Medicines List, TSML (2009), Tatarstan Formulary List, TFL (2009).

We used Microsoft Access for list comparisons and developed a database of lists. We calculated portions (percentages) of coincidences and discrepancies. We performed quality analysis of discrepancies according to WHO Essential Medicines Concept.

**Results:** The expansion rates over 10 years of the 21st century exceeded WHO EML expansion rate (320 to 349) by 3 times (TFL, 578 to 695), by 8 times (REML, 421 to 658), and by 10 times (RSML, 367 to 493). TSML had the highest percentage of WHO essential medicines (45%) and the TFL had the broadest EML coverage (67%). The RSML had the lowest indices for both WHO essential medicines inclusion (26%) and the EML coverage (27%). Comparison of listed medicine numbers revealed discrepancies. The discrepancies were uniform through the lists with RSML being the most problematic and reflected vulnerability to pharmaceutical promotion.

**Conclusions:** Development of national pharmaceutical policy was urgently needed with adoption of WHO Essential Medicines Concept as the core component of health reform.

**Funding source:** No specific funding

**Post scriptum:** These results were presented at the conference Quality information for quality use of medicines – QiQUM, 15-16 October 2010 and published in the Conference proceedings, which were forwarded to the ministers of health and social development, of science and education and to the head of the federal vigilance body with the Conference resolution. The outcome: the Federal meeting on development of Russian pharmaceutical Policy has been scheduled for December 10, 2010.

## Objective/Study question

To compare medicine lists, effective in Tatarstan and Russia, with WHO Model List of Essential Medicines (EML) and identify problems in medicine selection.

Since the latest Russian Essential Medicines List (REML) was developed with the sole purpose of regulating medicine prices, the comparative analysis was intended to assess if this policy could contribute to better access and use of medicines.

## Conflict of interest statement

Authors declare that there is no conflict of interest.

## Introduction/Background

The medicines situation in Russia changed dramatically since early 90th. The number of registered medicines kept increasing with every year. According to the Federal health-surveillance structure – Roszdravnadzor – 19 433 medicinal products were registered in Russia by March 2010. The attention of Government to pharmaceutical issues has dramatically increased: Governmental funds have been allocated and governmental projects of Supplementary medicines provision for selected patient categories and project "Health" have been initiated. However, the question if these investments have contributed to health and longevity remains unanswered. Paradoxically in the situation of the global financial crisis the medicine prices in Russia kept growing exceeding all highest world prices making out of pocket payments of Russian citizen and state medicines expenditures unprecedentedly high. The latest update of the Russian Essential Medicines list aimed to tackle this medicine pricing disaster in the country and to regulate prices for essential medicines. This is ironic in the view of the history of health care and Essential Medicines Concept development. After publication of the first WHO Model List of Essential Medicines in 1977, the World Health Assembly adopted its 31.32 resolution urging the member-states to develop national essential medicines lists in 1978. In the same year the International Conference on Primary care held in Alma-Ata (USSR) adopted the historical Alma-Ata Declaration on primary care, requiring immediate action from governments with focus on provision of essential medicines and vaccines as the most important component of required health system changes. The WHO Model List of Essential medicines has been universally recognised as the basis for national lists regardless of countries' level of economical or social development. The new time for the post-soviet countries with its changes required re-evaluation of strategic approaches to health and adoption of Essential medicines concept as the core component of the ongoing health reform.

With the aim to identify problems with development and functioning of medicines lists we sought to analyze positive medicines lists which have been officially in action in the health system of the Republic of Tatarstan in 2009 to contribute to the rational use of medicines and health system development.

## Materials and methods

We compared positive medicines lists effective on the territory of the Republic of Tatarstan (RT) in 2009 with the 16th WHO Model List of Essential Medicines (2009), WHO EML. There are four positive medicines lists effective in RT:

- The list of essential medicines approved by the Russian Federal Government (the order from 30 December, 2009) – Russian Essential Medicines List, REML.
- The list of medicines served by prescriptions of a physician or physician's assistant for provision of supplementary free of charge medical care to designated categories of citizens, having rights to state social help (the order of the Ministry of health and social development of the Russian Federation dated 18 September, 2006 N 665 with later changes) – Russian Supplementary Medicines Lists, RSML.
- The list of medicines, medicinal devices, specialized diet meals for the citizens entitled to provision of free of charge medicinal products, in accordance with the order of the government of Republic of Tatarstan N 315-p from 16 March, 2009 – Tatarstan Supplementary Medicines List, TSML.
- The formulary list of medicines of the Republic of Tatarstan, 5<sup>th</sup> edition, 2009 – Tatarstan Formulary List, TFL.

In addition, we compared all the lists with each other.

We used Microsoft Access for medicines lists comparisons and developed a database of medicines lists. To enable computer assisted comparisons we unified the names of medicines on the lists by manual editing of the lists in the Russian language. For example, we replaced the Russian name "nitroglycerine" with the international non-proprietary name (INN) "glyceryl trinitrate", we unified sequence of nouns and adjectives where appropriate. The editing process was carried out by two authors independently in a "blind" manner with subsequent manual matching of the edited lists. Altogether we formulated 25 queries to the database for coincidences on the lists and differences between the lists.

We analyzed the listing of medicines by medicine names (INNs, where available), dosage forms or formulations were not accounted for.

We calculated portions (percentages) of coincidences and differences. We performed quality analysis of differences according to the WHO Concept of Essential Medicines.

## Results

Of particular interest were the WHO Essential medicines which were not listed on any of the analyzed acting positive lists. We identified 97 entries (see Appendix 1):

- 22 were vaccines and immunoglobulins, the nomenclature and use of which have been traditionally regulated in Russia by special alternative normative documents;
- 17 were intestinal anthelmintics, antifilarials, antiangiardiasis, antischistosomals and antitrematode, antipneumocystosis and antitoxoplasmosis, antielshmaniasis and antileprosy medicines – medicines for diseases which do not present major public health problems in Russia;
- 12 were medicines for malaria, HIV-infection and tuberculosis (including fixed combinations);
- 10 were dermatological substances;
- 6 entries for contraceptive purposes; and
- 2 medicines for management of addictions – methadone and nicotine for replacement therapy.

## Results

Table 1  
Numbers of entries on positive medicines lists effective in the Republic of Tatarstan compared to the WHO Model List of Essential Medicines in the 21st century (by year)

Year	WHO EML [22]		TFL		TSML		RSML		REML					
	Year	Number	Year	Number	Year	Number	Year	Number	Year	Number				
1999	308	[24]	2000	[25]	578				2000	[8]	421			
2002	320	[24]	2002	[25]	665	2002	[19]	404	2002	[9]	505			
2003	316		2004	[25]	669			2004	[13]	367	2003	[10]	531	
2005	315		2006	[25]	677			2005	[20]	525	2005	[12]	612	
2007	320		2008	[25]	695			2006	[15]	445	2007	[21]	493	
2009	349					2009	[5]	278	2008	[4]	360	2009	[14]	500

Table 2  
Percentages of inclusion of WHO essential medicines and WHO EML coverage by positive lists effective in the Republic of Tatarstan

TFL		TSML		RSML		REML	
% WHO essential medicines included	WHO EML coverage	% WHO essential medicines included	WHO EML coverage	% WHO essential medicines included	WHO EML coverage	% WHO essential medicines included	WHO EML coverage
34	67	45	36	26	27	42	60

We have identified 16 groups on the TFL which included the "me too" medicines with the numbers in brackets:

- 5HT<sub>3</sub> receptors blockers (2);
- sulphonamides for diabetes mellitus: (5);
- low-molecular weight heparins: (3);
- calcium channel blockers (dihydropyridine derivatives): (3);
- ACE inhibitors: (6); • angiotensin II receptors antagonists: (2);
- statins: (2);
- colony-stimulating factors: (3);
- NSAID, oxicams: (3);
- bisphosphonates: (4);
- general anaesthetics halogenised: (2);
- antidepressants, non-selective monoamine reuptake inhibitors: (3);
- antidepressants, SSRIs: (4);
- combination of long-acting beta 2 agonists with glucocorticoids: (2);
- anticholinergic broncholytics: (2);
- systemic antihistamines: (8).

The number of "me too" entries varied from 2 to 8 with the updated of 3 [2, 4], and average of 3.38 (+1.71).

## Conclusions and Policy implications

- WHO Essential Medicines Lists have been successfully used in the health system of the Republic of Tatarstan as a model instrument since 1999.
- The number comparison revealed discrepancies between the lists which require urgent development of national pharmaceutical policy based on the WHO Essential medicines Concept.
- The content discrepancies are uniform through the positive lists effective in the Republic of Tatarstan with the Russian supplementary medicines list (RSML) being the most problematic and reflect the vulnerability to pharmaceutical promotion.
- Policy recommendations for the health system of the Republic of Tatarstan include revision of the Tatarstan supplementary medicines list (TSML) and the formulary list (TFL) on the basis of the WHO EML with fast-track deletion of medicines not meeting the WHO essentiality criteria, further development of selection process according to the WHO model, and introduction of state pharmaceutical policy.

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