

What Do We Know About Drug Supply of Russian Population? And What Do We Want ...

Report of the Formulary Committee of The Russian Academy of Medical Sciences

It was submitted on February 12, 2009

Immediate answer

- Nothing in general
- Many details

Over 10 years:

- There are several concurrent analytical groups on drug supply in our country – RMBC, Pharmexpert, DSM Group
- They analyze “market of drugs” – how many drugs were sold, which drugs were sold more
- Pharmaceutical companies are their target audience
- They do not have a “focus on patient”
- Physicians know almost nothing about them

The principled position

- Drug supply is not a market
 - The International Community recognized the failure of **market principles** in drug supply
- Our main task is to understand – not how many drugs were sold and were dispensed, but how many drugs were received by the consumer – patient**
- We are looking for equity in health care**

Pharmexpert

- In 2007 32% of the Russian pharmaceutical market (in the amount of about 3.8 billion U.S.D.) was the share of the State programs:
- 17% – for the drug reimbursement program (DLO)
- 15% – for inpatient medicines

RMBC

- In 2007 drug sales in terms of DLO amounted to 51.15 billion rubles.
- It is lower than sales in 2006 for 30 %.
- The proportion of DLO sector in total Russian pharmaceutical market decreased to 16% in 2007 (in 2006 - 25%).

Pharmexpert

In January 2009 the commercial sector of pharmaceutical market grew by 25,5% in rubles and decreased by 5,2% in U.S.D. Its volume amounted to 815 million U.S.D., or 26,4 billion rubles.

As for drug packages, there was a decrease in the commercial sector of pharmaceutical market (-7%), the actual amount of sold drugs - 305 million packs.

The Ministry of Industry and Trend

- In 2004-2005 the market grew at a rate of 30% per year (mainly due to DLO)
- In 2007 there was a growth of 7-8% in the pharmaceutical industry
- It is the evidence of emerging recession

Board of the Accounting Chamber of the Russian Federation:
the results of the audit of effectiveness of the public funds application to ensure drug supply of population (from producer to consumer) for the period of 2006-2007

- In 2007 there was a worsening of drug supply for citizens.
- The proportion of prescriptions for dispensed drugs to citizens decreased from 94,8% in 2006 to 88,3% in 2007, in some regions - only 70%.

June 20, 2008

Board of the Accounting Chamber of the Russian Federation

...the absence of efficient mechanisms for restricting the registration of unreasonably high prices? of foreign producers in the RF?, did not make it possible !to save! the federal budget funds approximately at least of 3 billion rubles in 2006-2007.

There are no people behind these figures!

Today we have no patients:

- we know about 6 thousand patients with hemophilia, but in fact there are 14 thousand patients;
- we know about 4-5 thousand patients with Willebrand disease, but in fact there are 1.5 million patients ;
- only 13% of patients with diabetes mellitus have an adequate treatment;
- so on, so forth...

We do not know where are our patients.

Accessibility of essential medicines will increase their number in 2-10 times !

We have already seen it after the implementation of DLO

Goals of the report of the Formulary Committee of The Russian Academy of Medical Sciences

- To reveal poorly discussed issues
- To discuss the availability of drugs to population
- To give principled recommendations for changing the current situation

In this presentation

- All points and sections of the report will not be discussed
- Full version is available at the web-site WWW.RSPOR.RU

Basic principles of the drug supply system

- Equity in availability of drugs
- Focus – on patient
- Simplicity and clarity of the system
- Stability of the system
- Scientific basis of the system
- Application of the decision-making methodology

Equity in availability of drugs

Essential medicines – for everyone

Special attention – to vulnerable groups

Focus – on patient

The basis of drug supply system – standards and protocols of medical care

Simplicity and clarity of the system

- Clear and understandable rules
- Harmonization within the system and with international technologies

Stability of the system

- Long-term contracts
- Reference prices
- Reduction of risks

Scientific basis of the system

- The quality management system
- Standardization in Health Care

Application of the decision-making methodology

- Evidence-based medicine
- Clinico-economic analysis
- The “rule of square” in decision-making
- Authority for the health technology assessment– the Formulary Committee of The Russian Academy of Medical Sciences

Project: essential medicines for everyone

- The cost of all essential medicines should be defrayed by different budgets (state, subject of the RF, compulsory health insurance)
- Each essential medicine has single price covered by the State–reference price
- Drugstores and distributors receive payment for work and services in storage, transportation and distribution of essential medicines to the patient
- The development of the domestic pharmaceutical industry is concentrated to the production of essential medicines
- The administration of essential medicines should be included into strict standards and protocols of care
- The Formulary Committee of The Russian Academy of Medical Sciences is given functions of the National Authority for the health technology assessment

The cost of all essential medicines should be covered by different budgets

- total 330 items of vital drugs**
- The List of Essential Medicines (2007) includes 652 items of drugs.
 - 138 items of drugs belong to inpatient sector (general anesthetic, most antibiotics, etc.)
 - 41 drugs have no evidence of effectiveness.
 - There are a lot duplicate drugs, which do not differ significantly on its efficacy and safety (1-2 drugs instead of 6-7 drugs can be included into one group).
 - After removal of inpatient and ineffective drugs, and removal of duplicate drugs the List will include about 300-330 essential medicines.
 - Among 330 essential medicines there are 181 drugs, which costs are almost entirely defrayed by public funds: the Program on 7 Orphan Diseases (17 items), medicines for treatment of mental diseases and epilepsy (32 items), anticancer drugs (77 items), drugs for the treatment of diabetes (19 items), bronchial asthma (7 items), HIV infection (24 items), tuberculosis (5 items). After its removal the List will consist of 100-150 drugs.
 - Only 100-150 drugs are not covered entirely by public funds.
 - The main consumers of essential medicines are so-called “preferential categories of citizens”, the number of “consumers” of 100-150 drugs will not be significantly increased.

Each essential medicine has one price covered by the State – reference price

- Reference prices for all drugs according to INN (all items of enalapril)
- Reference prices for all drugs of one group (all ACE inhibitors)
- The State assumes the cost of drugs on a fixed reference price
- If the price of a drug is higher than the reference one (original drug instead of generic) – consumer pays the difference between prices
- The mechanism of setting the reference price –
 - on the price of the cheapest drug,
 - on the average price,
 - comparison with reference prices in other countries
 (or example, prices in the British National Formulary are reproduced in the Medicines Handbook the Formulary Committee of The Russian Academy of Medical Sciences 2009).

The model of reference price of ACE inhibitors

- The difference in enalapril and perindopril cost: 2,5 rubles for the daily dose of enalapril against 26 rubles for the daily dose of perindopril with comparable efficiency
- Taking the average price of enalapril as the reference price for all ACE inhibitors we will get the average price of ACE inhibitors - 2,5 rubles for the daily dose
- There are 12 million patients with arterial hypertension in our country
- With the introduction of reference prices 2,5 rubles \ daily dose the State spending would be 10.8 billion rubles per year, i.e. will be compatible with the existing spending (6,6 billion rubles for 2 drugs)
- Only 10-20% patients with arterial hypertension receive the full treatment, hence the real spending on ACE inhibitors will be 1-2 billion rubles per year instead of current 9.5 billion rubles per year (including heart failure)

Drugstore and distributor receive payment for work and services in storage, transportation and distribution of essential medicines to the patient

- **Payment for services is fixed and does not depend on the cost of drugs**
- **The payment may depend on the complexity of storage (special conditions), length of haul, high risks associated with short shelf life**
- **Payment for the Commodity Distribution Network is provided by the State funds**

Alternative

- **Patient pays for services obtaining medications at the drugstore (for example no more than 50 rubles per prescription),**
- **The limit of such co-payment can be fixed, for example 1000 rubles per year, then – the State grants**
- **Pensioners and patients with chronic diseases may have a full subsidy for co-payment**
 In 2007 the drugstore segment of the market of drugs amounted to 7.4 billion U.S.D., about 190 billion rubles.
 Trade margin reaches 20% in drugstores, in absolute terms - not less than 38 billion rubles per year
 If 30 million people will pay 50 rubles per month for a prescription, the total amount of payment for pharmacy services will be 1.5 billion rubles per month or 18 billion rubles per year – it is about 1 \ 2 of the existing income of drugstores

The development of the domestic pharmaceutical industry is concentrated to the production of essential medicines

Most of essential medicines have already being produced by the domestic pharmaceutical industry, thus the program will serve as motivation for its development.

Sales of essential medicines guaranteed by the State will serve as an additional incentive for the production of raw materials and ready forms with expiring patents .

The development of new essential medicines (including both raw materials and ready forms) should be financed by the State, possibly through the public-private partnership.

A special place - for orphan drugs

- **The List of Orphan Technologies had been developed by the Formulary Committee of The Russian Academy of Medical Sciences in 2005, and it is constantly updated**
- **The needs of the country in Orphan Drugs had been calculated**
- **The project of the Government Program on Orphan Diseases including the development of domestic pharmaceutical industry was worked out by the Formulary Committee of the Russian Academy of Medical Sciences (will be discussed on June 17, 2009)**

The administration of essential medicines should be included into strict standards and protocols of medical care

Nowadays there are 600 approved standards and about 40 approved protocols , there are about 600 projects of standards and about 100 – of protocols.

The application of this documents has been assimilated by medical organizations, there is an interest and experience of companies which provide IT-technologies for the implementation of standards into electronic medical cards, the system of quality management, economics and the paperwork in Health Care

The team which has established the system of standardization for Russian Health Care 19 years ago, is entirely weaned off of this work.

All the principles and ideas had been stolen and distorted: the stolen has never brought happiness to the thief.

The Formulary Committee of The Russian Academy of Medical Sciences is given functions of the National Authority for the health technology assessment

The Formulary Committee of The Russian Academy of Medical Sciences has been being an independent expert authority for the assessment of medical technologies for 12 years.

The List of Essential Medicines, the List of Orphan Medical Technologies, Negative List of Medical Technologies, Outpatient and Inpatient Drug Formularies, Pediatric Drug Formulary have been worked out for these years, governing documents for the evaluation and selection of Health technologies, harmonized with the international technologies in this area, have been developed.

Numerous reference books, monographs, guidelines, standards have been published, schools and seminars for teaching principles of clinico-economic analysis and evidence-based medicine are held

Significant additional benefits of the project

- There is no corruption component in it: patients and physicians stop selling preferential drugs, there is no collusion between them, it reduces the influence of pharmaceutical companies on the prescription of definite drugs (there is a lower number of it, but the State have to pay the same sum of money anyway, not every patient is ready to extra cost for the brand without valid justification).
- It reduces the "paper" work of physicians, there is need to know much about the system of "discounts", to complete a set of accounting forms etc., it releases time for medical activities.
- In the typical case a responsible nurse may write out a prescription.
- Monitoring of the proper administration of drugs and writing out prescriptions becomes simpler.
- The issues of government procurement are removed.

Financing and cost of the Program

- Implementation of reference prices will reduce the cost of existing programs at least on 20-30%, elimination of unnecessary drugs – on another 20%.
- The administration of tough prices and assortment of drugs will release about 50% of funds from the existing financing system. These funds will be sufficient to implement the Program in 2009.
- In 2010 the necessary cost should be converted according to exchange rate, because the majority of essential medicines are imported one, and they will not be substituted soon.



We wish all our humanistic ideals and thoughts were not boiled down to the issues of benefit and commerce



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