

Value of new drug assessment during market access in Russia

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Which drugs are paid in Russia?

- Provision with essential drugs (ONLS) – ONLS list
- Regional benefit – region's own list of drugs
- «7 nosologies» - there's 17 medications
- Also there is separate Vital and Essential Drug List (approved by Government of RF in the latter case in 2007), hospital drugs are paid according to this list - 655 medications. It correlates with ONLS

Large quantity of drugs without proven effectiveness is used in Russia

- 40 from 655 drugs from Vital and Essential Drug List have no proven effectiveness
- In 2007, about 20% of outlay in addition provision of drugs (DLO) were spent on drugs without proven effectiveness, according the opinion of experts of Formulary Committee of Russian Academy of Medical Sciences
- Population spends money for nonsense at all

Table – top 10 drugs

Ministry of Health Care and Social

Development breaks of all scientific activity

- In 2007, MoH stopped standardization in public health in fact, standards of medical care are not approved
- Specialists of standardization are separated from their work
- Normative documents, regulating the development of Vital and Essential Drug List on the basis of proves of effectiveness and pharmacoeconomics, are not used. They are replaced with “copying”, but inexact documents
- In 2009, the development of protocols of care was stopped
- MoH does not interact with progressive scientists, councils, and structures, namely with Russian Academy of Medical Sciences

How decisions are made?

- In Russia the treatment of Gaucher's disease is financed (200 000 EURO in year per patient, 160 patients)
- In Russia the treatment of inhibitor haemophilia is financed (1.3 billion EURO in year per patient, 40 patients)
- But mucopolysaccharidosis (I and II types) is not financed (200 000 EURO in year per patient, 100 patients) – several children die every year

How decisions are made?

- Arbitrarily, according to politic moment
- DURING LAST 5 YEARS THE PROGRAM OF FINANCING DID NOT INCLUDE ANY NEW EFFECTIVE DRUG (ONCOLOGY, RHEUMATOLOGY, HEMATOLOGY)
- MoH propose searching charitable organizations as an answer for all requests for help
- A FORMAL OR UNFORMAL SERVICE FOR HEALTH TECHNOLOGY ASSESSMENT IN STRUCTURE OF MINISTRY OF PUBLIC HEALTH AND SOCIAL DEVELOPMENT IS ABSENT

Health technology assessment in Russia

- There is no any formal service in Ministry of health structure
- There is no understanding that such service is necessary
- The Formulary Committee has been working at the evaluation of medical technologies for 12 years

The Formulary Committee – HTA activities

- Evaluation of applications for inclusion of drugs in the List of essential drugs, Orphan drugs and in Negative List from producers and experts
- Placing applications at the web-site
- Standard procedure of evaluation
- Three levels of examination (secretariat, professional group, presidium)
- Decision-making by consensus