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- МЕТОДОЛОГИЧЕСКИЕ ОСНОВЫ ФАРМАКОЭКОНОМИЧЕСКОГО МОДЕЛИРОВАНИЯ
- РЕЗУЛЬТАТЫ РОССИЙСКИХ ФАРМАКОЭКОНОМИЧЕСКИХ ИССЛЕДОВАНИЙ
- МАТЕРИАЛЫ X НАЦИОНАЛЬНОГО КОНГРЕССА С МЕЖДУНАРОДНЫМ УЧАСТИЕМ «РАЗВИТИЕ ФАРМАКОЭКОНОМИКИ И ФАРМАКОЭПИДЕМИОЛОГИИ В РОССИЙСКОЙ ФЕДЕРАЦИИ» 4-5 апреля 2016 г., г. Нижний Новгород

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XVIII ANNUAL EUROPEAN CONGRESS OF INTERNATIONAL SOCIETY FOR PHARMACOECONOMICS AND OUTCOMES RESEARCH, 7-11 NOVEMBER, MILAN

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Abstract: *Main presentations and educational seminars which took place during Annual European congress of International Society For Pharmacoeconomics and Outcomes Research (ISPOR) are covered.*

Key words: *ISPOR, pharmacoeconomics, health technology assessment, health economics, cost-effectiveness analysis, cost-utility analysis, innovation in oncology, orphan drug, HTA agencies, medical devices, multi-criterial decision analysis.*

Specialists in the pharmacoeconomics, health technologies assessment, health economics, representatives of the pharmaceutical society and other experts explored more than 2450 presentations during XVIII Annual European congress of International Society For Pharmacoeconomics and Outcomes Research (ISPOR) which took place in Milan, Italy in November 7–11. 5220 people from 90 countries visited the congress.

At the plenary meeting were discussed the issues of decision-making strategy on medical technologies using lifecycle approach. Senior Medical Officer of European Medicines Agency (EMA) Hans-Georg Eichler notes that it is necessary to expand the horizons of HTA research, noting that the system of assessment of medical technology needs to be improved, in particular, he notes that it is necessary to take into account the needs of future patients when performing ongoing research. He also stresses the need to improve interaction between regulatory agencies and HTA agencies.

At the section «Defining and Valuing Innovation in oncology» were covered the following questions:

- what does the term "pharmaceutical innovation in Oncology" include?;
- what difficulties and inconsistencies arise during use of this definition?;
- how different agencies (FDA, EMA) evaluate innovative cancer drugs?;
- is there a relationship between this definition and the market price of cancer drug?

Researchers show the degree of innovation and criteria for the definition of drugs to each group, as well as the difficulties encountered in determining this degree due to the nature of the tested drugs, which does not always give you the opportunity to evaluate a new connection entirely. It is noted that the degree of innovativeness can be carried out in various ways, including the achievement of the end points. Also a comparison of FDA and EMA decisions was condcuted, the results of which show that each agency uses its own criteria for classifying drugs in the innovative group.

Orphan drugs have received special attention in the lecture "Orphan drug evidence requirements for positive HTA recommendations", which was presented to the list of orphan drugs German regulatory Agency G-BA for the period 2012-2015, approved on the basis of the collected evidence. The peculiarities of drugs in the treatment of rare diseases were covered. Attention is drawn to the fact that there are no specific criteria for the identification of orphan drug, which creates certain difficulties in the approval process of these drugs.

The section "Possible increased synergy between health technology assessment (HTA) and regulatory agencies: opportunity or challenge for medical devices? " and " Assessment of the value of medical devices: can we simply apply established processes for drugs or do we need to pursue separate processes for devices?" were devoted to the peculiarities of the evaluation of medical products.

It is noted that medical devices are crucial in the prevention, diagnosis and treatment of illness and rehabilitation. The experts note that the market for medical products is increasing every year in scope, more than 10,000 applications for assistance shall be filed to the European patent office (EPO) every year. The European Union (EU) from year to year maintains about 3,500 new technologies, of which 500 belong to the third class of medical devices (medical products with a high degree of risk, are in direct contact with organs or parts of body systems). Also, in 2014, were published 365 of HTA reports from 12 European countries, 78% of which considered medical devices, and in other cases, in vitro diagnostics, and imaging (MRI, ultrasound, etc). The researchers noted that from 2000 to 2006. mainly used HTA cochlear implants, and by 2013 an increased interest in the evaluation of wound dressings. This trend is apparent in countries such as France, Germany, Sweden, Austria, etc. In this regard there is a need to establish priorities in the selection of medical devices.

It was noted that when entering the market, developers of medical devices in many countries are faced with some problems. For example, buyers purchase only the goods of mass demand, since entered the market, extrapolating evidence of effectiveness first entered the market products to the whole class later. Health facilities in the provision of medical care in hospital faced with the fact that, expensive medical equipment pays for itself after hosting a number of procedures. Therefore, many countries need economic analysis and HTA to justify the pricing and privileged access. Development processes and decision making can proceed in parallel and influence each other.

In the framework of the session "What is the role of economic evaluation in pricing and reimbursement of medicines? A comparison between England, Germany and France" discussed the role of economic evaluation in the pricing and reimbursement of medicines, also specialists from England, Germany and France presented the structure of pricing in their countries.

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Also, several seminars were devoted to multi-criterial decision analysis (MCDA). In the session "Multi-criteria decision making in the Central & Eastern European (CEE) region: are we there yet?" were discussed issues concerning the development and application of MCDA. In the report of the representative of Slovenia pointed out that the State chamber of insurance Institute of Slovenia uses MCDA solely for internal purposes and will continue to support the improvement and implementation of MCDA. The representative of Ukraine made a presentation about the first steps of the implementation of the MCDM (Multi-Criteria Decision Making) in the context of the HTA in 2015, also presented the first MCDM model for Ukraine, based on the adapted international.

A poster session also took place during the congress and it was attended by lecturers and graduate students of the Department of medicinal provision and pharmacoeconomics. It should be mentioned that Russian studies were interesting for the representatives of various international companies and organizations.

Best General Poster Research Presentations were assessed. Three works were awarded:

- Resource utilisation and costs in patients with post-stroke spasticity in the United Kingdom Raluy-Callado M, Cox A, MacLachlan S, Gabriel S, Dinet J
- Comparative effectiveness on cardiovascular outcomes of metformin initial therapy and add-on second-line drugs among patients with type 2 diabetes Kim Y, Ko M, Jo A, et al.
- Scoring and responsiveness of the self-assessment of treatment version II questionnaire in patients with painful diabetic peripheral neuropathy van Nooten FE, Trundell D, Staniewska D, Revicki DA

The organizers and members of the committee congratulated the winners and wished them further success.