INTRODUCTION:

In Bulgaria, the regulatory body sets for the first time legal requirements for Health Technology Assessment (HTA) in Law on Medicinal Products in Human Medicine (LMPHM) on 27 June 2015. The next essential step for HTA capacity building was the promulgation of Ordinance 9 / December 1, 2015 on the conditions and procedures for conducting health technology assessment by the Ministry of Health (1). In the beginning of 2016, the Main Price and Reimbursement Committee was set and launched a process for establishing the small working groups with the task of reviewing the first applicants reports of pharmaceuticals for inclusion in the Positive Drug List (PDL).

METHODS:

The objective of this study is to summarize the recommendations of the newly established HTA Committee in Bulgaria and to examine the characteristics of the technologies and the key considerations that led to those decisions. We systematically read all published by the Committee recommendations for 2016 and analyzed them under: type of recommendations (positive or negative for inclusion in PDL), population, specialization, type of service, type of justification and the impact on final conclusions.

RESULTS:

For the first year of its work the HTA Committee was able to assess fifteen technologies (pharmaceuticals) and only one received a negative recommendation (6 percent) from the working group. All the rest (n = 14; 94 percent) were recommended for funding. The final recommendation from the Main Price and Reimbursement Committee is available for four (27 percent) technologies – all positive for inclusion in PDL. All recommendations were connected with adults and in oncology (n = 4; 27 percent); heart diseases (n = 4; 27 percent); Chronic Obstructive Pulmonary Disease, COPD (n = 2; 13 percent); diabetes (n = 2; 13 percent); psoriasis (n = 2; 13 percent); Hepatitis C (n = 1; 7 percent). The only negative recommendation was justified due to lack of robust evidence, safety issues and credibility of HTA analysis (2).

CONCLUSIONS:

The information about the number of applications received from the Committee is not available and correct conclusions about the capability is not possible, but indirect circumstances, as the lack of well-trained HTA experts, certainly impede establishment of the small working groups and slow the assessment process (3). At this point it is clear that additional efforts are need to overcome the barriers and smooth adoption and implementation of HTA methods in Bulgaria.

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PP072 Applying Sensitivity Analysis For Robust Choice Of Health Technologies

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INTRODUCTION:

The aim of this work is to evaluate the stability and robustness of the solution obtained at the end of the

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Health Technology Assessment (HTA) process by conducting a sensitivity analysis. Sensitivity analysis allows identification of the elements representing the source of uncertainty and to determine the impact of this variability on the stability of the assessment results, in order to provide more adequate and objective support to decision-making process.

METHODS:

A new method for health technologies evaluation, Decision-oriented HTA (1), which integrates the Analytic Hierarchy Process (AHP) (2) in the model Core Model® of the European Network for HTA (EUnetHTA) was taken into account. In this context, a mathematical model was implemented to conduct a sensitivity analysis on weights and on performance values of the technology alternatives evaluated. The objective is to evaluate the effects on AHP results induced by a change on initial values of each criterion of the decision-making model. Sensitivity analysis was carried out by calculating the minimum changes of the weights and performances needed to reverse the current ranking of alternatives technologies (3).

RESULTS:

This approach was applied to some technology assessment studies such as video-laparoscopy, femtosecond laser, da Vinci robot, to test their efficacy and reliability. It is very important to perform a sensitivity analysis and assure the stability of the solution when the performance values associated to the technology alternatives are close because, in this case, a small change of performance values reversed the ranking of alternatives technologies.

CONCLUSIONS:

Applying sensitivity analysis to such decision-making processes is essential to ensure the consistency of final decisions. This evidence has shown that this method allows for a more rapid interpretation of results, thus facilitating the choice of decision-makers about the decision to invest or not in new technology.

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PP075 Has A Drug Replacement An Impact On Hospital Treatment? A Health Technology Assessment-debate

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INTRODUCTION:

Drug product changes occur in hospitals for different reasons: improved efficacy or tolerance of a drug, reduced costs, new pharmaceutical innovations or drug shortage (1). The aim of this analysis is to develop a process model for drug product changes and to determine a hospital specific threshold when product change is reasonable, provided that the efficacy and safety of the new product is economically reasonable (2).

METHODS:

The individual process steps at the Klinikum rechts der Isar in Munich (MRI) were recorded to develop a process model. The required expenditure of time for the different process modules was documented and a process cost calculation undertaken.

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