

Opinion

НАЦИОНАЛЕН ЦЕНТЪР ПО ОБЩЕСТВЕНО ЗДРАВЕ И АНАЛИЗИ	
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On Ph.D. thesis for the doctoral program *Social medicine and health management*

PhD candidate: **Anelia Hristova Nikolova**

Title: **Study and analysis of the health technologies assessment process and economic aspects since the introduction in Bulgaria**

Supervisors: Prof. Ilko Getov, Ph.D.

Assoc. prof. Evgeni Grigorov, Ph.D.

General presentation of the procedure and the candidate

The presented set of materials on paper / electronic form is in accordance with Article 70 (1) of the Regulation on the terms and conditions for acquiring scientific degrees and holding academic positions in the National Center for Public Health and Analysis.

In connection with the dissertation, the doctoral student has attached 4 full-text publications. All documents are presented and meet the requirements of ZRASRB (Law for the development of the academic staff in the Republic of Bulgaria) and the Regulations of the National Center for Public Health and Analysis.

Anelia Nikolova was born on September 24, 1979. She graduated with a bachelor's degree with a professional qualification "economist" in 2002 at Varna Free University "Chernorizets Hrabar", and in 2017 graduated in the master's program "Pharmaceutical Management" at the Medical University - Varna. The doctoral student has extensive professional experience in the field of healthcare - she has held the position of a chief expert at the Sofia Regional Office of the National Health Insurance Fund and at the National Center for Public Health and Analysis.

Relevance of the topic

The Ph.D. thesis presented for discussion by Anelia Nikolova entitled " Study and analysis of the health technologies assessment process and economic aspects since the introduction in Bulgaria " is relevant to the scientific and practical interests in the field of market access of innovative medicines and medicines cost management in modern healthcare systems.

The dissertation is written on 152 pages altogether. It is illustrated with 95 figures, 8 tables, and 1 appendix. The bibliography consists of 142 bibliographical sources, covering all significant publications of Bulgarian and foreign authors on the topic.

The dissertation is entirely within the scope of the doctoral program and the professional field. The content, the volume, the conducted research, and the conclusions are exhaustive, the individual elements are well-balanced.

Study methods

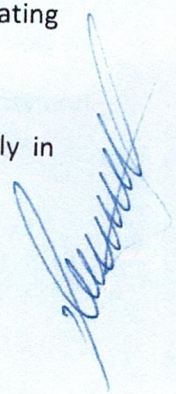
The scientific hypothesis is correctly formulated. The 6 tasks correspond to the purpose of the dissertation - to perform a comprehensive analysis of the introductory stage of institutionalization, organization, and implementation of HTA in Bulgaria and the economic aspects of its application, deriving the key factors for development and effective management.

Characteristics and evaluation of the dissertation and the contributions

The thesis presents a literature review with a volume of 48 pages on the individual elements of the topic, using 142 contemporary Bulgarian and foreign bibliographic sources. The literature review is extremely extensive, as the Ph.D. student has examined in depth the concepts of health technology assessment, as well as the different approaches and good practices in Europe. The review concludes with an analysis of the requirements and the structure of the process in Bulgaria.

The materials and methods used in the dissertation are exhaustively listed. Historical, sociological, and statistical methods are used, each of which is described in detail, indicating the aim of the individual studies.

The results of the research are presented comprehensively, consistently, and logically in Chapter IV of the dissertation. The set tasks have been completed.



1st task:

The first task of the dissertation is to provide a historical review and analysis of the process of HTA worldwide. It is presented in the literature review section of the dissertation.

2nd task:

The process of performing HTA was monitored - from the submission of an application by the Marketing authorization holder (MAH) of the medicinal product to the approval of the HTA report, defining the key stages, obstacles, omissions, and weaknesses. The organizational structure, the main participants, and the compliance with the regulatory requirements are presented in detail. The average duration of HTA procedures and the influencing factors are analyzed.

3rd task:

The prerequisites for successful preparation of a draft report on HTA have been assessed, incl. provision of experts and their opinion, organization of the work of the working groups, and the terms for carrying out the evaluation. The register of HTA experts of NCPHA was analyzed. A separate chapter is also devoted to the members of the working groups, tracing the evolution of their staff for the period under review, as well as the main problems that the administration has encountered in appointing them.

4th task:

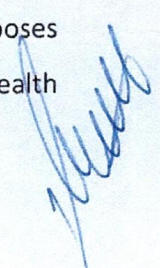
An in-depth analysis of the results of the activity for assessment of health technologies for the period 2016 - 03.2019 was conducted. The number of the procedures, the therapeutic areas, and the results of the process were monitored.

5th task:

The economic aspects of the introduction of the HTA process in Bulgaria were analyzed by expected budgetary impact and the average cost per medicinal product by therapeutic area.

6th task:

Guidelines and recommendations for improving the HTA process at the national level and in the context of the EU legislative initiative have been formulated. The Ph.D. student proposes an addition to the scientific definition of HTA, namely that: "The evaluation of health



technologies leads to the optimization of decision-making for reimbursement of health services, as well as to the saving of public funds."

Evaluation of the doctoral student's publications and personal contribution

4 full-text publications have been published on the topic of the dissertation. In 3 of the publications, Anelia Nikolova is the first author.

The scientific production of the doctoral student meets the requirements of the NCPHA for the acquisition of a doctoral degree.

There is a high erudition of the dissertation on the issue, evidence that the research is a personal contribution, representative of the country, and specific recommendations, contributions, and practical benefits can be derived.

In general, the presented dissertation for the acquisition of a doctoral degree by Anelia Nikolova meets the requirements, it is up to date and will be the basis of future research in the field.

Abstract

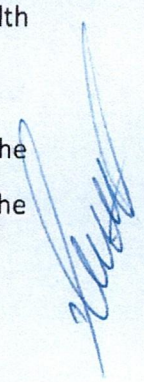
The presented abstract is made according to the requirements of the National Center for Public Health and Analysis and reflects the main results achieved in the dissertation.

Conclusion

The dissertation contains **scientific-theoretical and applied-practical results, which represent an original contribution to science** and meet all the requirements of the Law for Development of the Academic Staff in the Republic of Bulgaria. The presented materials and dissertation results fully comply with the specific requirements adopted in connection with the Regulation of the NCPHA for the application of the Law for Development of the Academic Staff in the Republic of Bulgaria.

The dissertation shows that the doctoral student Anelia Nikolova has in-depth theoretical knowledge and professional skills in the scientific specialty Social Medicine and Health Management by demonstrating qualities and skills for independent research.

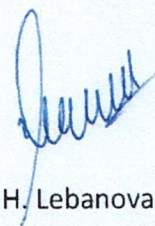
Due to the above, I confidently give my **positive assessment** of the research presented by the above-reviewed dissertation, abstract, results, and contributions, and I **recommend** the



esteemed scientific jury to **award the educational and scientific degree 'Doctor'** to Anelia Hristova Nikolova in a doctoral program in Social Medicine and Health Management.

02.12.2020

Reviewer:

A handwritten signature in blue ink, appearing to be 'H. Lebanova', written over the printed name below.

/Assoc. Prof. H. Lebanova, PhD/