

## OPINION

for his dissertation "*Study and analysis of the process of assessment of health technologies and economic aspects of the introduction in Bulgaria*" presented for public defense before a scientific jury for awarding an educational and scientific degree "Doctor" by **Anelia Hristova Nikolova**, PhD student of independent training in the scientific specialty "Social Medicine and Health Management " at NCPHA.

**REVIEWER:** Prof. Dr. Petko Nenkov Salchev, MD - Directorate "Classification Systems, Standards and Innovation", National Center for Public Health and Analysis.

Selected as a reviewer of the presented dissertation on a meeting of the scientific jury appointed by order RD 417 / 11.2.2020, at Director NCPHA, pursuant ZRASRB , PPZRASRB and art. 72, para. 1 of the Regulations on the terms and conditions for acquiring scientific degrees and holding academic positions in the NCPHP.

### SCIENTIFIC SUPERVISORS:

Prof. Ilko Getov, Ph.D. and Assoc. mag. farm. Evgeni Grigorov, MD

### DATA FROM THE PROFESSIONAL AUTOBIOGRAPHY OF THE DISSERTANT

#### University education:

In 2002 he graduated with a bachelor's degree in International Economic Relations in from the Varna University "Chernorizets Hrabar".

In 2017, she acquires a master's degree Master's degree in Pharmaceutical Management from the Medical University "Prof. Dr. Paraskev Stoyanov "- Varna.

He has a recognized post graduated specialty in "Medical Informatics and Health Management" in 2020.

#### Professional experience:

She started his professional career as a financier in a bank in Sofia. From 2014 to 2016 she worked as a chief expert in the Sofia Health Insurance Fund, Pharmacies Department, Medicinal Products Sector. From 2016 until now she has been working as a Chief Expert at the Classification Systems, Standards and Innovations Directorate at the NCPHP, Health Technology Assessment Department, and subsequently at the Healthcare Professionals Analysis and Assessment Department.

Since 2010 she has passed many specialized courses to acquire additional competencies and skills.

Fluent in English language, uses a very good level of German.



## **EVALUATION OF THE PRESENTED DISSERTATION WORK**

### **1. Relevance of the problem**

The dissertation of Anelia Nikolova is dedicated to a current problem before our modern health system, namely the analysis of the process of Health Technology Assessment (HTA) and the economic aspects of the introduction in Bulgaria.

Modern models of health systems face a number of challenges related to the demographic trends of an aging population, an increase in chronic diseases and the need to ensure a better quality of life and reduce the risk of cardiac patients. The growth rate of health care spending is significantly higher than GDP growth in most countries and economies. This puts even developed economic countries to the test, which also find it difficult to finance their healthy conservation. Therefore, the need for assessment, early diagnosis, prevention and prevention of diseases minutes, reducing and controlling costs for their treatment are extremely important issues for the health system and society.

And the collected topic of the dissertation is significant - both from a scientific and from an applied-practical point of view. The medical and social significance of the drug policy, as well as the elaboration of practical approaches for its introduction in the Bulgarian healthcare, can serve as a basis for making informed decisions in developing and approving a strategy for reducing the costs of medicines in our country.

### **2. Structure, layout of the dissertation and abstract a**

The presented dissertation is structured according to the respective instructions. The dissertation contains 144 pages and is illustrated with 95 figures and 8 tables. The bibliography includes 142 literary sources, in Cyrillic and Latin.

The dissertation includes an introduction, literature review, hypothesis, goal, tasks, materials and research methods, analysis of results, conclusions and recommendations, contributions, bibliography.

The literature review is 47 pages long. It accurately and systematically presents the most important issues related to the developed problem. The way in which the literature review is illustrated by the use of numerous figures and photographs, which make it possible to trace the development of all aspects of health technology assessment internationally and nationally, makes a good impression.

The literary review is based on over a hundred sources by Bulgarian and foreign authors. The dissertation includes publications that are relevant for the last 5 years. The materials used convince in the good knowledge of the topic by the dissertation. The citations are correct and accurate. In general, the literature review confirms the in - depth preliminary preparation of A. Nikolova on the developed problem. The language is clear and precise.





The creative assessment of the literary material crystallized at the end of the review with the presented findings about the state of the assessment of health technologies in Bulgaria and the conclusions about the state of the problem. Anelia Nikolova summarizes the relevance and importance of the introduction of the OST process in our country, as necessary actions that governments and regulators take in this regard, aimed at ensuring rational drug use and controlling public spending on medicinal products.

Analyzing the data from the literature review, the doctoral student logically reaches the goal of his research and accurately and clearly formulates the tasks for its implementation.

The presented abstract, which reproduces in sufficient volume the dissertation work, has a clear and accurate literary language and fully reflects the developed issues and conclusions.

### 3. Purpose, tasks and methodology of the research

The aim and tasks in the dissertation are formulated precisely and correspond to the title. Included are six tasks that are specific and consistent implementation of raises fundamental purpose and verification of pledged hypothesis. The set tasks required the implementation of the author's own contribution of research. The object and the subject of the research are clearly and precisely defined.

The author examines the data from the scientific literature on the available scientific information worldwide regarding the assessment of health technologies. The next step is to collect data and present a comprehensive analysis of the institutionalization, organization and implementation of HTA in Bulgaria. A. Nikolova also studied the economic aspects of the application of the process, highlighting the key factors for its development and effective management.

### 4. Results and discussion

The obtained results are well presented and illustrated on 73 pages and fully cover all the tasks set by the dissertation. In this section the text is also well illustrated in tables and figures. The obtained results are correctly interpreted.

The nine main conclusions presented by A. Nikolova characterize the obtained results in detail. They are clearly and precisely formulated and are the result of precise implementation of the set goal and tasks of the dissertation.

The dissertation has significant contributions of theoretical-cognitive and applied nature. The main contributions are:

1. *For the first time in Bulgaria the organization of the implementation, the expert and administrative potential and the difficulties in the assessment of the health technologies have been studied and analyzed in detail.*



2. *Based on a thorough review of the modern scientific literature, the features, advantages, difficulties and challenges in the assessment of health technologies, as well as the prospects for the future are highlighted.*
3. *An algorithm has been developed and presented for a detailed description of the organization and stages of the process, procedures and rules for work, the importance of expert potential and resources, and the experience gained related to the assessment of health technologies.*
4. *The main factors that influence the duration of the procedures, the quality of the reports are defined and a comprehensive assessment of the organization of the HTA process in Bulgaria for the first THREE years of the introduction in practice is made.*
5. *Opinions and attitudes about motivation for participation and the most common problems and difficulties of the experts in working committees for evaluation of health technologies are studied and summarized.*
6. *The expected economic aspects of the introduction of post-HTA medicinal products by periods, rate of increase of costs, therapeutic areas, saved costs of rejected drugs, average cost of treatment with new drugs by years and others that can serve as a starting point are shown. point of further studies of the effect of HTA in the country.*
7. *A critical analysis and commentary was made on the advantages, disadvantages and the expected impact of the changes concerning the legislative framework, introduced after 31.03.2019.*

I have no remarks and recommendations to the presented results and conclusions. Anelia Nikolova uses the obtained data competently, and the analysis is objective.

4 publications follow from the dissertation, as two of the publications are in a journal referenced and indexed in a world-famous database.

### **Assessment of the professional and personal qualities of the doctoral student**

I appreciate her theoretical knowledge and practical skills. In the course of the development of the dissertation, she demonstrates skills for working with literary sources, methodological and computer literacy, as well as teamwork necessary for the successful development of the doctoral dissertation. Nikolova has developed her analytical capabilities in the design of scientific publications and communications, has shown abilities for their attractive presentation.

Anelia Nikolova is able to apply the scientific methods of analysis and synthesis, shows skills for in-depth study of the available literature, masters the application of the methodology in the development of the dissertation and in the correct interpretation of the available data and facts.

### **6. Conclusion**

With the development of the dissertation topic Anelia Nikolova has set herself an ambitious task, which she has done excellently. The dissertation **contains scientific and scientific-applied results, which represent an original contribution and meet all the requirements** of the Law for development of the academic staff in the Republic of Bulgaria (ZRASRB), the Regulations for application of ZRASRB. The presented materials and dissertation results **fully** comply with the specific requirements for application of ZRASRB. The dissertation is fully completed, written in





professional and literary language with accurate expression. The dissertation meets the necessary criteria for awarding the educational and scientific degree "Doctor" under ZRAS.

The dissertation shows that the doctoral student Anelia Hristova Nikolova **has** in-depth theoretical knowledge and professional skills in the scientific specialty, **demonstrating** qualities and skills for independent research.

Due to the foregoing, confidently give its **positive assessment** of the presented above dissertation, abstract, results and offerings, and **offer** a scientific g Uri to assess and positive thesis "*Study and analysis of the process of assessment of health technologies and economic aspects of the introduction in Bulgaria*" for awarding the educational and scientific degree "DOCTOR" to the dissertation Anelia Hristova Nikolova, for which I will personally vote positively.

City. Sofia

01.12.2020 on

Prepared by: .....

/ Prof. Dr. Petko Salchev, MD /