



REVIEW

from

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NATIONAL CENTER OF PUBLIC HEALTH AND ANALYSES, SOFIA
OF DISSERTATION WORK FOR AWARDING PhD Degree

Elected a member of the scientific jury by order № RD-417 / 02.11.2020 of the Director of NCPHA

Area of Higher Education: 7. Health and sports

Professional field: 7.1 Medicine

Doctoral program: "Social medicine and health management"

Author: ANELIYA HRISTOVA NIKOLOVA - PhD student in independent training

Directorate: "Classification systems, standards and innovations" at NCPHA

Topic: "STUDY AND ANALYSIS OF THE PROCESS FOR EVALUATION OF HEALTH TECHNOLOGIES AND ECONOMIC ASPECTS OF THE INTRODUCTION IN BULGARIA"

Scientific advisers:

Prof. Ilko Getov, PhD

Assoc. Prof. Evgeni Grigorov, PhD

1. General presentation of the procedure and the doctoral student

The review was prepared in accordance with the requirements of the Academic Staff Development Act in the Republic of Bulgaria and the regulations for its implementation, as well as the Regulations on the terms and conditions for acquiring scientific degrees and holding academic positions in NCPHA.

In connection with the procedure, I was provided with a set of materials on paper and electronic media, which includes the required documents, as follows:

- dissertation work
- abstract
- copies of scientific publications
- list of publications and participation in scientific forums
- other documents

The doctoral candidate has submitted 4 publications and 1 participation in a scientific forum.

Anelia Hristova Nikolova is enrolled as a PhD student in self-study by Order of the Director of NCPHA № RD-147, as of March 8, 2019 under a doctoral program: "Social Medicine and Health Management".

The doctoral candidate has the required number of points, according to Appendix 1. Minimum national requirements for scientific and teaching activities.

At a joint Scientific Collegium of the Directorates "Classification Systems, Standards and Innovations" and "National Health Data and e-Health", extended according to Order

RD-387 / 15.10.2020 of the Director of NCPHA with three external habilitated persons, experts on the topic of the dissertation work, and on the basis of a decision of the Scientific council, the doctoral candidate was expelled with the right to defense according to Order № RD-416 / 30.10.2020 of the Director of NCPHA.

The set of documents meets the requirements, I know the course and development of the educational process and the discussions related to the development and results of the dissertation. The submitted documents prove the legality and completeness of the conducted training and the procedure for its administration.

2. Brief biographical data about the doctoral student

Anelia Hristova Nikolova was born in 1979 in the city of Sofia. In 2002 she graduated with a degree in International Economic Relations from Varna Free University "Chernorizets Hrabar", graduated with a bachelor's degree in economics. In 2017 she received a master's degree in "Pharmaceutical Management" from MU-Varna, and since June 2020 she has a recognized medical specialty "Medical Informatics and Health Management".

Her career began in the banking sector. From 2014 to 2016 she worked as a chief expert in the Sofia Health Insurance Fund, Pharmacies Department, Medicines Sector. Since 2016, 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. Her research interests are in the field of social medicine and public health, pharmacoeconomics, pharmaceutical legislation and innovation in the field of healthcare.

She has excellent computer literacy and speaks English.

3. Evaluation of the dissertation

- Characteristics of the dissertation

The doctorate is well structured, according to the specifics of the chosen scientific field and meets the requirements of "Appendix 2. Recommended requirements for dissertation work for obtaining the educational and scientific degree PhD of the Regulations on the terms and conditions for acquiring scientific degrees and taking academic positions at the National Center for Public Health and Analysis.

It contains 152 pages, 7 sections, incl. application, multiple tables, figures, photos, etc. 142 literary sources in Cyrillic and Latin are cited. The dissertation is illustrated with 95 figures, 8 tables and 1 appendix. The conducted research, in-depth analyzes and the obtained results determine the main contributions of the dissertation. The ratio of the parts of the dissertation is balanced, as the own works are presented on a total of 94 pages (61%).

The defined purpose and tasks of the dissertation work are included in the scientific specialty of the doctoral program, correspond to the content and the conducted researches. The methods and materials of the researches are correctly selected and exhaustively described, which achieve a good balance from the point of view of the future application of the contributions (scientific-theoretical and scientific-applied), formulated by the dissertation.

- Topicality of the theme

The dissertation work submitted for evaluation examines in depth and comprehensively the process of Health Technology Assessment in the country and the economic aspects of its introduction.

The overall organization of the HTA process in Bulgaria for the period from its introduction in the country to the change in the Bulgarian legislation in 2019 are reviewed, commented and analyzed.

The dissertation for obtaining the educational and scientific degree PhD of Anelia Hristova Nikolova entitled "Research and analysis of the process of assessment of health technologies and economic aspects of the introduction in Bulgaria" is a current and effective research. The work will be of great interest to the experts in the field of HTA, as well as to the health managers related to the drug policy in our country. In addition, it should be emphasized that modern pharmaceutical practice and regulation need such in-depth, analytical and substantive studies to outline the positive directions and trends to be followed in changing the regulatory framework and setting priorities in health management and spending public funds on it.

- Knowledge of the problem

The paper provides a literature review on the topic, using Bulgarian and foreign sources.

The choice of the topic, in my opinion, is conditioned by the direct participation and interests of Anelia Nikolova in the administration of the HTA process in Bulgaria, as she also has a lot of practical knowledge and experience related to it.

The dissertation provides comprehensive information about the state of the problem in the field in which the dissertation works, in order to outline its contribution. The scientific work has a positive value and contains opportunities for the realization of a number of important for healthcare projections of the payment of innovative health technologies with public funds.

Various aspects of the HTA process are analyzed - the procedural course of the process, the deadlines for HTA, the register of experts participating in the working committees, the results of the activities with their indicators of volume and quality, and results of completed procedures. The economic indicators are analyzed in two perspectives - budgetary impact of the introduction of new drugs by therapeutic areas and by years and the average cost of treatment in the respective therapeutic area. The doctoral student presented an extremely interesting and detailed analysis - a comparison of the legislative framework concerning HTA before and after March 31, 2019, which I believe can serve as a basis for future decisions.

Own research is comprehensive and properly structured. It dominates as a volume in the dissertation. The historical framework of the study is impressive and covers the emergence and historical development of HTA in Bulgaria and Europe, various European initiatives and organizations related to HTA, the introduction of HTA in Bulgaria, regulations and more.

The good argumentation and the in-depth analysis of the content and the comparative comparison with other European countries follow the development trends of the HTA process.

The first steps in the introduction of the HTA process in Bulgaria, which was followed in the period 2016-2019, are indicated. A comparison of the different stages is made.

Special attention is paid to the specifics of selection and work of the HTA Commission and the working groups of external experts. Many articles and materials and a large number of normative and sub-normative acts, which have regulated HTA during the whole period of its

introduction in our country, have been analyzed. The analysis shows the excellent awareness of the dissertation about the research problem.

The author's style is fascinating, the terminology is correct, and the methodological apparatus is consistent with the specifics of the scientific field.

- **Research methodology**

The section with research materials and methodology is presented on a total of 4 pages and includes a description of the research methods used, object and subject of the research, data sources, materials and statistical techniques, where appropriate, according to the dissertation chapters.

Regarding the study of the knowledge and attitude to the HTA process by experts and outsiders, the method of direct individual anonymous online-based survey with a questionnaire was used, which is presented as an Appendix to the dissertation.

I believe that the methodological apparatus used is sufficiently comprehensive, allows the achievement of the set goal and the realization of the research tasks. For the purposes of the doctoral thesis, a sufficiently acceptable level of response to the set six tasks and a scientific hypothesis has been obtained.

- **Purpose, tasks, conclusions and recommendations**

The aim of the study is to make a comprehensive analysis of the introductory stage of institutionalization, organization and implementation of HTA in Bulgaria, as well as the economic aspects of the application, deriving the key factors for development and effective management.

To achieve this goal, six main tasks are set:

1. To make a historical review and analysis of the HTA process worldwide.
2. To monitor the process of performing HTA - from the submission of an application by the company holding a marketing authorization (MAH) of the medicinal product to the approval of the HTA report, defining the key stages, obstacles, omissions and weaknesses.
3. To analyze the prerequisites for successful preparation of a draft report on HTA, incl. provision with experts and their opinion, organization of the work of the working commissions and the terms for carrying out the evaluation.
4. To study the reports of the working commissions for establishing compliance with the requirements and procedures, submitting a report, making a final decision and to formulate the factors influencing the HTA process.
5. To analyze the economic aspects of the introduction of the HTA process in Bulgaria.
6. To formulate guidelines and recommendations for the improvement of the HTA process at national level and in the context of the legislative initiative in the EU.

Getting acquainted in detail with the results of the dissertation I find them very valuable and informative.

The tasks have been performed on the basis of the conducted analyzes and the results of them have defined the main conclusions and recommendations, namely:

- The evaluation of health technologies leads to optimization of decision-making for reimbursement of health services, as well as to saving of public funds.
- The organization of the HTA process is very good, despite the low resource security.

- A key factor for the development of HTA should be the awareness of the need for quality evaluation by all stakeholders.

- It is necessary to continue attracting highly qualified specialists to be involved in the HTA process.

- It is necessary to build a system for training experts.

- MAHs should be involved in the establishment, financing and maintenance of disease registries.

The formulated conclusions and recommendations are a summary of the conclusions in the different parts of their own research; they are in accordance with the research and the results, follow the set and completed tasks and I fully accept them.

I accept the results obtained and the conclusions and recommendations made in the dissertation, which follow logically from the set goals and objectives. The challenge for the author to be correctly and comprehensively formulated contributions to the dissertation has been achieved. I appreciate with dignity the formulated contributions of scientific-theoretical and scientific-applied nature.

In the present study, a complete analysis and assessment of the organization and process of HTA in Bulgaria is made. The key factors for the further development and management of the process are presented.

The presented data have an in-depth analytical, substantive and confirmatory nature, showing the preferred areas of the industry for innovation, the results in practice of gaps and oversights in regulation and serious and quality work on administering a large number of HTA procedures in a relatively short time and without having serious experience and capacity for it.

- Assessment of publication activity

The presented evidence for publication activity of the doctoral candidate exceeds the requirements of the Regulations of NCPHA for the formation of a decision for positive assessment in the procedure for obtaining the educational and scientific degree PhD. In connection with the dissertation, 4 publications in Bulgarian peer-reviewed and indexed periodical scientific journals and 1 participation in an international scientific forum were presented. The quantitative requirements are covered, and in 3 of the publications the doctoral candidate is the first author. The total number of points by indicators according to "Table 1. Minimum required points by groups of indicators for different scientific degrees and academic positions" to the Regulations on the terms and conditions for obtaining scientific degrees and holding academic positions in the National Center for Public Health and Analysis is 51.

4. Evaluation of the abstract

The author's abstract of the dissertation for the acquisition of Anelia Nikolova's PhD degree reflects the conducted research and meets the requirements. The specifics of the obtained results, the emphasis of the research and the applied methods are in a field that requires special training and attitudes. An obvious fact is the deep understanding of the specific matter of the dissertation and the support of supervisors.

The proposed abstract reflects the essence of the dissertation, is properly structured and made according to the requirements of NCPHA.

5. Conclusion

The dissertation contains important scientific and applied results, many of which can be used as a basis and model for conducting drug policy to improve the organization and effectiveness of HTA in Bulgaria, both for medicinal products and for extending the scope to other procedures, activities and products.

The dissertation meets all the requirements of the Law for the Development of the Academic Staff in the Republic of Bulgaria and the specific requirements of the Regulations of the NCPHA. The dissertation has in-depth knowledge and skills to be the basis of future research.

Based on the above, I confidently give a positive opinion and propose to the Honored Scientific Jury to award the educational and scientific degree PhD of Anelia Hristova Nikolova in the scientific specialty "Social Medicine and Health Management" at NCPHA.

Prof. Plamen Dimitrov, MD, PhD
Sofia, 12 November 2020

