

STANDPOINT

Presented by

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concerning the PhD Thesis developed by Anelia Hristova Nikolova on the topic:

**„Investigation and Analysis of the process for Health Technology Assessment and
Economic Aspects of its implementation in Bulgaria”**

for acquiring the educational and scientific degree "PhD" in the scientific specialty "Social
Medicine and Health Management"

Scientific Supervisors

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The PhD Thesis presented by Anelia Hristova Nikolova is dedicated to the investigation and analysis of the process of assessment of health technologies and economic aspects of their implementation in Bulgaria. The Thesis contains a total of 152 pages, it is visualized by 92 figures, 8 tables and 1 annex. The Reference list contains 142 scientific sources published in Cyrillic and Latin alphabets.

The scientific work fully complies with the Rules for conditions and procedures for acquiring and occupying academic positions at the National Center for Public Health and Analyses and contains the following chapters: Introduction; Literature Review; Aim and Tasks; Materials and Methods; Results and Discussion; Conclusions, Recommendations and Contributions, References and Annexes.

Recently the rate of growth of health expenditures has been substantially higher than the Gross Domestic Product increase rate in most countries. A permanent trend of annual growth of health expenditures in the aspect of value and as relative rate of the total national budget is evidenced. Thus even economically developed countries meet more and more difficulties in funding their health systems. Such increase of total health care funds, including medicinal treatment, is observed in Bulgaria as well.

The increase of medicinal products costs is a natural process substantiated by a number of factors that could be divided into two main groups:

- Ageing population, increasing number of patients with non-communicable diseases, elevating public expectations (strive for contemporary and more effective treatment) and more population demands;



- Available innovative therapies, increased and, in a number of cases, irrational application, polypragmasia, insufficient abiding to therapy and ineffective management of drug expenditures.

The resources for pharmacotherapy should be managed in a way providing access to all patients who really need it.

The public resources appointed for drugs should be distributed in the most equitable way, ensuring balance between public and individual interests, keeping the interest of the pharmaceutical industry on the particular national drug market.

The expenditures for medicinal products increase constantly in all European countries and the measures for sustaining them are more and more on politicians' agenda that, on their part, should ensure a smooth rate of costs increase or reduction without challenging healthcare quality. The relevant activities undertaken by managers and regulators aim to ensure rational drug use and to control the public expenditures for medicinal products. Those activities and initiatives are targeted at all involved in the system guaranteeing a fairer distribution of the risk for overdraft of the already limited financial resources. The implementation of the process for health technology assessment (HTA) is such effective mechanism for ensuring expenditure effectiveness.

Health Technology Assessment is a proven scientific methodology. It assists health managers, governmental officials and politicians in making substantiated decisions for the reimbursement of novel diagnostic and therapeutic approaches, medicines and medical products. Clinical trials data, complying with the proposed cost, number of target patients and potential expenditures enable the acquirement of information for the relative value (cost) effectiveness of the novel health technologies, such as medicinal products, medical devices and health services. In most cases a comparison is made between the available standards (or options) for patients' treatment and care. HTA is realized with the help of analytical frames based on clinical, epidemiological and health-economic information in order to define the best way to distribute the limited healthcare funds.

HTA process was really started in Bulgaria in the beginning of 2016, covering only medicinal products.

Legally the process was arranged by Ordinance № 9 of 01.12.2015 for the conditions and procedures HTM assessment technologies (repealed).

In Bulgaria the HTA process is an intermediate step after issuing an authorization for use before the inclusion of the medicinal product in the positive drug list (PDL). This process is mandatory.

According amendments to Art. 259, Para. 1, P. 6 of Law for Medicinal Products in Human Medicine (LMPHM - Drug Act) (State Gazette No. 102 of 2018, enforced 01 January, 2019), since 01.04.2019 the national body performing HTA in Bulgaria is changed. Art. 259 of the Drug Act states that the National Council for Costs and Reimbursement of Medicinal Products (NCCRMP) is engaged

with performing the activities on health technologies assessment and this procedure is part of the process of inclusion in PDL.

The acquired more than 3-year experience in the period February 2016 – March 2019 enables the investigation and analysis of the reported benefits, disadvantages and mistakes at the implementation of the process in the country with a view to formulation of conclusions and actions for targeted, effective and reasonable application of the HTA tool in payment for medicinal and non-medicinal therapy, diagnostic and other therapeutic and rehabilitation procedures in the future.

At this stage it is important to report and outline the key moments and issues following from the implementation of HTA in Bulgaria in this three-year period in order to consider them in the further development, improvement and enhancement of the assessments scope.

The aim and tasks are clearly and precisely formulated.

The aim of the present work is to make a comprehensive analysis of the introducing stage on institutionalization, organization and implementation of HTA in Bulgaria and the economic aspects of its application, outlining the key factors for development and effective management.

The following tasks have been identified for the realization of the aim:

1. Elaboration of a historical review and analysis of global HTA process.
2. Tracing the HTA process – from the application of the company – owner of authorization for use (OAU) of the medicinal product to the approval of the HTA report, identifying the key stages, occurring obstacles, omissions and shortcomings.
3. Analysis of the prerequisites for successful compilation of a draft report for HTA, including experts' involvement and their opinions, organization of the work commissions; activities and deadlines for submitting the assessment.
4. Survey of the work commissions reports for establishing compliance with the requirements and procedures, submission of a report, final decision-making and formulation of the factors affecting HTA process.
5. Analysis of the economic aspects of HTA introduction in Bulgaria.
6. Formulation of directions and recommendations for the improvement of HTA process at national level and in the context of EU legislative initiatives.

The comments on the obtained results are correctly formulated, well-grounded by relevant data. The conclusions follow logically the cited results corresponding to the basic accents of the presented PhD Thesis.

The main contributions provided by the Thesis are scientific-theoretical and applicable in practice.

The presented abstract of the PhD Thesis reflects the most essential elements of the conducted study.

Five scientific publications and presentations at scientific forums have been made referring to the PhD Thesis.

My opinion is that the PhD Thesis presented by Anelia Hristova Nikolova is genuine and is elaborated personally by the PhD candidate. It corresponds fully to all requirements of the Law for Development of the Academic Staff in the Republic of Bulgaria (LDASRB), Rules for its implementation and Rules for the conditions and procedures of acquiring scientific degrees and occupying academic positions at the national Center of Public Health and Analyses for awarding the educational and scientific degree "PhD" in the defined scientific specialty.

In conclusion, evaluating the relevance of the discussed issue, comprehensive survey, logical presentation of the results and argumentation of the outlined conclusions, my evaluation for the conducted study, presented as a PhD Thesis, abstract of the PhD Thesis, achieved results, realized publications and contributions is positive. I propose to the Honorable Scientific Jury to award the educational-scientific degree "PhD" to Anelia Hristova Nikolova.

Sofia

25 November 2020

Prepared by:

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