O P I N I O N

on a dissertation for awarding the educational and scientific degree “doctor” in professional field 3.8 Economics, scientific specialty “World Economy and International Economic Relations”


Regarding: participation in a scientific jury grounded on order № RD 06-61/29.04.2024 of the Rector of the University of Economics - Varna, issued on the basis of a decision of the Faculty council of the Faculty of Management (protocol №12 from 29.04.2024); appointed to prepare an opinion at the first meeting of the scientific jury, held on 09.04.2024.

Author of the dissertation: Ralina Dobrinova Mircheva (PhD student at the Department of International Economic Relations, UE-Varna)

PhD thesis: „Specifics of the international activity of companies from the pharmaceutical industry in Bulgaria“

1. GENERAL PRESENTATION OF THE DISSERTATION.

The presented scientific work consists of a total of 222 pages, with 196 pages dedicated to the main text, 12 pages for the list of references, and 10 pages for the appendices. The analysis is accompanied by 47 figures and 23 tables. The volume, structure, and style of the presentation of this scientific product provide grounds for classifying it as a dissertation work that presents an independent scientific research.

In the preparation of the dissertation, 139 sources were used, with 80 of them being scientific publications and the remaining 59 being normative documents, analytical reports from official institutions, and other freely accessible sources on the Internet. Almost half of the scientific publications are in Bulgarian, while the rest are in English. I consider the sources used to be contemporary, reliable, and relevant to the problem of the scientific research.

The doctoral candidate has also submitted an abstract that objectively reflects the structure and content of the dissertation.

2. PUBLICATIONS AND PARTICIPATION IN SCIENTIFIC FORUMS.

Ralina Mircheva has promoted her scientific research by publishing one article in the journal "Izvestiya" (the English version) at UE-Varna and three conference proceedings, with one of them being co-authored. Two of the publications are in English. All the publications are indexed in secondary databases, including the National Academic Library and Information System (NACID) with an open access. In my opinion, the doctoral candidate complies with the criteria set forth in Article 2b, paragraphs 2 and 3 of the ZRASRB, as well as Article 35, paragraph 1 of PRAS at UE-Varna, considering the minimum requirement of 30 points, she has achieved 35 points.

From the publications, it is evident that Ralina Mircheva has participated in 3 scientific conferences. It is important to highlight that all three conferences were external to UE-Varna, which I consider to be highly positive in terms of promoting her scientific
achievements, especially considering that one of the conferences had international participation.

3. ASSESSMENT OF THE STRUCTURE AND CONTENT OF THE DISSERTATION.

The selected topic holds significance for various reasons. The pharmaceutical industry is characterized by a high level of globalization, making it crucial to comprehend the international strategies and operations of pharmaceutical companies. This understanding is essential for examining industry trends such as trade volume, research and investments in R&D, and more. Research in this area is vital for evaluating the effectiveness of regulatory frameworks, financial implications, and other related aspects. Furthermore, studying the international activities of pharmaceutical firms offers valuable insights into the industry's impact on healthcare systems and society. Despite being a relatively uncommon focus in academic literature, the doctoral student's dissertation and findings are particularly valuable for Bulgaria.

The dissertation delves into the specifics of pharmaceutical companies and their commercial operations in Bulgaria, with a precise definition of the research object and subject. The main goal is articulated clearly and expanded upon through 5 specific research tasks that are logically and analytically bonded. Furthermore, the inclusion of 4 research hypotheses not only adds practicality to the study but also contributes to its overall significance.

Typically, the dissertation adheres to a traditional format comprising of three chapters. It is composed in a scientific manner, yet manages to maintain an engaging and accessible tone. The arguments put forth are well-reasoned, with a coherent and well-structured thought process.

The introductory chapter of the study establishes the general context by exploring the influence of globalization on the pharmaceutical sector. This encompasses a wide range of factors, including market integration, pricing and dynamics, technological innovations, regulatory issues, pandemics, and global value chains. The examination of globalization naturally leads to the recognition of the need for supranational institutions and the regulation of both the production and trade of medicinal products, which is discussed as the second point. Subsequently, the author focuses on the specificities within the European Union, elaborating on this as the third point. Within the first chapter, particular attention is devoted to the processes of concentration and their effects, such as delayed research and development and cartelization. Lastly, the dissertation's argumentation is supported by referencing Covid-19 as an external stress factor in the pharmaceutical market. This underscores the significance of the pandemic in terms of its consequences on regulations, the organization of international production by companies, and, most importantly, as a test of the market's overall sustainability. Furthermore, it provides an opportunity to identify the weaknesses in its regulation and functioning.

In the second chapter of the thesis, the doctoral candidate explores and scrutinizes the unique characteristics of the market structure in which pharmaceutical corporations operate. This involves a comprehensive examination of regulations at national and EU levels, key players in the industry, supply chains, and notably, an in-depth analysis of parallel drug trade. This practice has increasingly become a pivotal factor influencing not only drug prices but also their accessibility, supply, and the strategic maneuvers of pharmaceutical companies.

The dissertation's primary scientific and applied contribution lies within its final chapter, which exclusively focuses on examining the drug market structure in Bulgaria and the international activities of companies, particularly those of foreign origin, operating within the country. To accomplish this, extensive databases were utilized, officially obtained from reputable sources such as the Customs Agency, IQVIA (a prominent global provider of
integrated health information and technological services utilized by all sector companies), and the Passport database (Euromonitor International's market research database). The data underwent thorough examination using cluster analysis, which substantiates the hypothesis of significant market structure shifts and international company operations resulting from the pandemic. Through descriptive analysis and in-depth interviews, the study successfully uncovers the dynamics, trends, and specific details of these changes. Ultimately, the research yields several noteworthy and somewhat surprising conclusions that carry substantial implications for the role of parallel trade. These findings are particularly relevant considering the ongoing debates and mounting pressure for additional regulations, including the possibility of a complete ban on parallel trade.

4. EVALUATION OF THE SCIENTIFIC AND APPLIED CONTRIBUTIONS IN THE DISSERTATION.

The contributions declared in the abstract I consider to be too general and more like a summary of everything accomplished in the particular stages of the dissertation. In my personal opinion, the essential contributions are contained in the final chapter and are expressed in the confirmation of the four research hypotheses, and the conclusions drawn on this basis, regarding the impact of Bulgaria's EU membership, the exogenous shock of Covid-19 on the pharmaceutical market, the importance of parallel imports, and generic drugs. Important conclusions regarding the market structure and its dynamics over the years are also found outside the doctoral candidate's hypotheses as a "side" result of cluster analysis.

5. PLAGIARISM IN THE DISSERTATION AND THE ABSTRACT.

Proper citation of literary sources has been ensured in compliance with the regulations. The presence of plagiarism has not been identified in the dissertation and abstract.

6. CRITICAL REMARKS AND RECOMMENDATIONS.

I give myself the liberty to express two critical comments:

1) The drugs market is exceptionally specific, primarily due to its strong regulation and the vast number of segments it encompasses. Unlike other product markets, these segments possess unique organizational and interaction mechanisms (such as prescription and over-the-counter; original and generic products; pharmacy and hospital; private and publicly funded; with free and controlled prices; based on pharmacological profile, etc.). All of these factors contribute to the daunting task faced by doctoral candidates when analyzing the market as whole. In my opinion, imposing preliminary limitations with a clear focus on one or several interconnected segments would have enhanced both the depth of analysis and the resulting outcomes, conclusions, and recommendations.

2) The study in the dissertation arrives at distinct important conclusions, offering responses to many questions that remain the subject of public and political debate. Interestingly, these conclusions have been overlooked by the doctoral candidate and have not been incorporated into the final conclusions and recommendations.

7. QUESTIONS TO THE DOCTORAL CANDIDATE.

The question I would like to pose to the doctoral student is as follows: What are the potential implications (for businesses, the market, and public finances) in Bulgaria of a potential shift from the current prescription system (based on the trade name of medicinal products) to a system based on international non-patent or pharmacopoeia nomenclature of the active pharmaceutical ingredient?

8. CONCLUSION.
The dissertation and the presented materials (abstract and publications) contain an independent scientific research with distinguishable applied results, which have a contributory nature and meet the requirements of ZRASRB and the PRAS at the UE-Varna. In-depth theoretical knowledge and practical competencies, including skills for conducting serious research using contemporary methods of analysis, have been demonstrated.

This provides me with a basis to recommend to the esteemed members of the scientific jury to award the educational and scientific degree of "Doctor" in the field of 3.8 Economics, specialization in “World Economy and International Economic Relations”, to doctoral candidate Ralina Dobrinova Mircheva.

20.05.2024 г.
Varna

Reviewer: Заличена информация съгласно 3ЗД и регламент (EC) 2016/ 679

/Assoc. Prof. Kaloyan Kolev, PhD/
OPINION

written by a member of a scientific jury
of a dissertation for the award of an educational and scientific degree "doctor" in a
professional direction 3.8. - Economics, doctoral program - World Economy and
International Economic Relations according to a procedure announced by the
University of Economics - Varna

1. General information
   - **person who prepared the opinion**: Assoc. Prof. Zdravko Lyubenov, PhD, Department
     of International Economic Relations in D. A. Tsenov Academy of Economics – Svishov;
   - **reason for writing the opinion**: order No. РД-06-61/29.04.2024 of the Rector of
     University of Economics – Varna, determining the Scientific Jury for the procedure for the
     public defense of a dissertation and the decisions of the first meeting of the Scientific Jury held
     on 09.05.2024, at 11:05 a.m. in a hybrid format, which determined the Chairman of the
     Scientific Jury and the members who will write reviews and opinions;
   - **author of the dissertation**: Ralina Dobrinova Mircheva- PhD student at the Department
     of International Economic Relations at the University of Economics - Varna with supervisors:
     Prof. Vesselina Dimitrova, PhD and Chief Assist. Prof. Petyo Bosnakov, PhD;
   - **topic of the dissertation**: Specificity of the international activity of the companies from
     the pharmaceutical industry in Bulgaria

2. General presentation of the dissertation (according to the requirements of art. 27, para. 2 of the Regulations for the Implementation of the Law on the Development of the Academic Staff in the Republic of Bulgaria)

   The presented dissertation is 218 pages long and includes: introduction (5 pages), main text
   in three chapters (185 pages), conclusion (5 pages), references (13 pages) and appendices (10
   pages). **It meets the requirements laid down in Art. 27, para. 2 of the Regulations for the
   Implementation of the Law on the Development of the Academic Staff in the Republic of
   Bulgaria.**

   The analytical focus of the dissertation examines an essential problem of our reality -
   people's health and the related trade and supply of medicine markets through imports. The
   skillful argumentation of the relevance of the topic is caused by the need to understand these
   processes. The concentration of attention on the reasons for their occurrence, the way of their
   implementation and the tools used and its effects, strengthens the registered scientific value of
   the dissertation, but also shows the possibilities of the doctoral student to evaluate a delicate
   area of human knowledge.

   In this context, the present dissertation can be defined as a timely study that incorporates
   both the theoretical foundations and the practical-applied supporting points for scientific
   illumination and the real display of trends in the researched field.

   **The purpose of the dissertation is appropriately formulated.** It is related to a study of the
   dynamics in the import and production of medicines in Bulgaria. **The tasks of the dissertation
   have been determined according to the set goal and have found their realization in the
   development. The object of research in the dissertation is the pharmaceutical companies that
operate on the Bulgarian market. The subject of research in the dissertation is commercial activity in the pharmaceutical sector and the changes that occur with significant changes in the external environment.

The main thesis and the research hypotheses are logical and directs the analytical focus in the exposition to adequately meet the necessary requirements of the conceptual part and the organized empirical material.

The scientific literature used is correctly cited. Serious studies of current Bulgarian and foreign specialized publications are convincingly shown.

A thorough critical analysis of the scientific literature was carried out and the author's positions with good arguments were confirmed.

A skillful handling of the tools of scientific research is observed.

3. Publications and participation in scientific forums: compliance with the quantitative requirements under Art. 35, para. 1, items 1-4 of the Regulations for the Development of the Academic Staff at Varna University of Economics (to meet the minimum national requirements for awarding the educational and scientific degree "doctor", according to Art. 2b, para. 2 and para. 3 of the Law on the Development of the Academic Staff in the Republic of Bulgaria)

From the presented documents and materials, it can be concluded that the publications and participation in scientific forums of PhD student Ralina Mircheva fully meet the quantitative requirements under Art. 35, para. 1, items 1-4 of the Regulations for the Development of the Academic Staff at Varna University of Economics and the minimum national requirements for awarding the educational and scientific degree "doctor", according to art. 2b, para. 2 and para. 3 of the Law on the Development of the Academic Staff in the Republic of Bulgaria:

- the doctoral student was dismissed with the right of defence;
- presented a dissertation meeting the requirements of Art. 34, para. 2 and 3 in the primary unit - Department of International Economic Relations at the Varna University of Economics;
- a decision was made by the primary unit, which discussed the dissertation, to open a procedure for its defence, in accordance with Art. 31, para. 1 and para. 2 of the Regulations for the Development of the Academic Staff at the Varna University of Economics;
- the main results of the research carried out on the topic of the dissertation work were published in one independent article in the refereed/indexed journal "Izvestiya" of the Varna University of Economics, two independent and one co-authorship reports in from international conferences published in collections registered in the National Reference List of contemporary Bulgarian scientific publications with scientific peer review;
- the doctoral student has collected 35 points from the four publications in editions registered in the National Reference List of contemporary Bulgarian scientific publications with peer review.

The three publications presented show a well-argued author's position and generally reflect the achievements of the dissertation.

4. Assessment of the structure and content of the dissertation (compliance with the requirements under Art. 34, para. 2 and para. 3 of the Regulations for the Development of the Academic Staff at the University of Economics - Varna), opinion on the correctness of the dissertation abstract and the lexical and stylistic characteristics of the dissertation

The dissertation work is structured in an appropriate way. Purposefulness and logic are established. Argumentativeness of the ideas has been achieved in it.
From a content point of view, *chapter one* draws attention to the basic characteristics of the global environment that affect the medicine trade.

In *the second chapter*, the PhD student presents the organization of the pharmaceutical business and medicine trade in Bulgaria.

*The third chapter* is dedicated to the analysis of the data on the import of medicines and the data on the activities of the international pharmaceutical companies operating in Bulgaria. The research hypotheses have been tested and interpreted and recommendations have been made for improving the activities of pharmaceutical companies operating in Bulgaria.

In *the conclusion*, the PhD student drew the main conclusions from the presented scientific research and made a summary about the issues under consideration.

I consider that *the dissertation corresponds to the requirements under Art. 34, para. 2 and para. 3 of the Regulations for the Development of the Academic Staff at the University of Economics - Varna.*

*The abstract correctly and accurately recreates the structure and content of the dissertation. It meets the requirements and demonstrates the doctoral student's ability to synthesize and summarize.*

5. **Identification and evaluation of the scientific and scientific-applied contributions in the dissertation**

I accept the scientific and scientific-applied contributions indicated by the doctoral student, which show in-depth theoretical knowledge in the investigated issues and the ability to conduct independent scientific research.

The main scientific and scientific-applied contributions in the dissertation work can be identified in the following directions:

- The theoretical knowledge in the field of the essence of regional integration and the impact of global factors on the development of the pharmaceutical business and its adaptation to the international environment has been enriched;
- The theoretical-methodological framework for research and analysis of the pharmaceutical industry and the impact of the dynamics of its development on the welfare of nations has been supplemented;
- A way to apply the analysis toolkit in international business in the pharmaceutical industry has been developed;
- Empirical research has been carried out through in-depth interviews and analysis of statistical data on the activities of international pharmaceutical companies in Bulgaria. On this basis, connections and dependencies are revealed, conclusions and recommendations for improving their work are drawn.

I consider that the mentioned contributions of the PhD student meet the requirements of the current regulations for obtaining the educational and scientific degree "doctor" in the Republic of Bulgaria.

6. **Detected or undetected plagiarism in the dissertation and the abstract**

I do not find any plagiarism in the dissertation work and it abstract.

7. **Critical notes and recommendations**

I don't have any critical remarks about the PhD student.

I recommend her to continue her work on increasing the possibilities of supplying the population with quality and effective medicines at an affordable price.
8. Questions to the dissertation candidate

The last four years have brought many upheavals and changes at all levels – global, international, regional, state. The pharmaceutical industry was also seriously affected, which had to respond quickly and adequately to everything that was happening. Do you think that happened?

9. Conclusion

The presented dissertation "Specificity of the international activity of the companies from the pharmaceutical industry in Bulgaria" authored by Ralina Dobrinova Mircheva meets the requirements for awarding the educational and scientific degree "doctor" according to the Law on the Development of the Academic Staff in the Republic of Bulgaria, the Regulations to it and the Regulations of the University of Economics - Varna.

The established convincing and clearly differentiated scientific achievements in the dissertation give me the reason to declare a categorical positive assessment and to recommend to the respected members of the Scientific Jury to support a decision "FOR" awarding the educational and scientific degree "doctor" in the doctoral program - World Economy and International Economic Relations of Ralina Dobrinova Mircheva.

20.05.2024

Member of a Scientific Jury:

/ Assoc. Prof. Zdravko Lyubenov, PhD /
OPINION

By Assos. Prof. Elka Ignatova Atanasova, Ph.D

Department of Health Economics and Management, Faculty of Public Health, Medical
University "Prof. Dr. Paraskev Stoyanov" - Varna

Member of Scientific jury in accordance with Order No. R- 06-61/29.04.2024. of the Rector of the
University of Economics - Varna

Regarding: Dissertation for the acquisition of the educational and scientific degree "Doctor
(PhD)" in professional direction 3.8. "Economics", Doctoral program "World Economy and
International Economic Relations".

Author of the dissertation: Ralina Dobrinova Mircheva

FROM THE PHARMACEUTICAL INDUSTRY IN BULGARIA

Supervisor: Prof. Veselina Vasileva Dimitrova, Ph.D

Pursuant to Order No. R-06-61/29.04.2024 of the Rector of the University of Economics - Varna,
I am included as an external member of the Scientific Jury, and by decision of its first meeting,
held on 09.05.2024, it was decided to prepare an opinion on the procedure to obtain the educational
and scientific degree "Doctor" with PhD candidate Ralina Dobrinova Mircheva – the full-time
doctoral student at the Department of International Economic Relations at the Faculty of
Management of the University of Economics - Varna.

General evaluation of the dissertation

The dissertation is developed in a volume of 196 pages, structured as follows: introduction, three
chapters, conclusion, list of the literature, and two appendices. The main text contains 23 tables
and 47 figures. One hundred and thirty-nine literary sources are used, of which 40 percent are
internet sites, and English language sources prevailed in general. The titles included in the
references indicate that the PhD candidate is well acquainted with the literature and regulatory
framework in the researched area of the pharmaceutical industry, which allows her to detect
potential problems, identify trends, and make recommendations to stakeholders.

Topicality and significance of the dissertation

I believe that the doctoral candidate justified the relevance of the chosen topic in the introduction.
The relevance of the dissertation is undeniable, as it focuses on the pharmaceutical industry, whose
importance for health systems is enormous and especially growing in periods of crisis. The
dissertation also covers the period of the health crisis caused by Covid-19, which makes it possible
to trace trends, actions taken, results achieved, and unresolved issues.

The limited number of scientific publications in our country regarding the international trade in
medicines opens a niche, which will be filled with the present study. Such studies are necessary
and contribute to raising awareness, tracking transparency in data, and discovering weaknesses
and contradictions in practices in the international trade of medicines, which provides a basis for substantiated proposals for the development of the pharmaceutical sector.

**Structure and content of the study**

The structure of the PhD thesis is logically consistent. The object and subject of the study are presented. The goal is briefly defined - to discover specifics and trends in the Bulgarian market in the import, production, and trade in medicines. To achieve the goal, five scientific tasks have been formulated, which lead to the fulfillment of the set goal. The author defines a basic thesis according to which parallel import and import of generics can ensure continuity of supply of medicines to ensure access to medicines by patients in the country. To confirm the main thesis, four hypotheses are formulated, which are validated with the selected methods and statistical analysis.

Appropriate research methods (quantitative and qualitative) are used, and the framework of limitations is correctly presented.

**Chapter 1** focuses on the characteristics of the global environment and their impact on the trade in medicines. The PhD candidate demonstrates good knowledge and analytical skills in elucidating the significance of globalization, regionalization, and economic well-being for the trade in medicines. The international organizations and alliances that set the regulatory framework for this trade are examined. Further, Ralina Mircheva emphasizes pharmaceutical transnational corporations, which are carriers of new trends in global competitiveness in international markets. The author concludes the chapter with an analysis and summary of the opportunities for the pharmaceutical sector and the negative effects caused by Covid-19 in the conditions of globalization.

**Chapter 2** is dedicated to the organization of the pharmaceutical business and trade in medicines in Bulgaria. The doctoral candidate thoroughly analyzes the inevitable harmonization of the country's legislative framework in the wholesale trade in medicines. The pharmaceutical structure and the main participants are presented, the main practices related to the drug policy are examined, and one of the key concepts in it is defined - "generic medicine". In order to understand the meaning and scope of the parallel trade in medicines, as well as the contradictory practices of the Bulgarian market, the author quite logically first presents the construction and functioning of supply chains in the wholesale trade.

In **Chapter 3**, Ralina Mircheva analyzes and tests the research hypotheses, referring to four main sources of information for the empirical study: data provided by the IQVIA company, data provided by the Customs Agency, data extracted from the trademap.org website, and the Passport database, which is Euromonitor International's market research base. To collect information and prove the hypotheses, qualitative methods (in-depth interviews) and cluster analysis are applied, the results of which show definite changes regarding the realization of supplies of medicines in Bulgaria. At the end of the chapter, conclusions and recommendations are made for securing the Bulgarian market with the necessary medicinal products.
Evaluation of the contributions

I do not accept the wording of the first three scientific contributions. The first contribution seems incomplete, as the author does not substantiate what has been achieved based on the extensive survey of theoretical views on the nature of regional integration. The logic of the second formulated contribution is violated - it is stated that the established statements and conclusions are also essential for proving the author's thesis and hypotheses. The third contribution should probably reflect the testing and interpretation of the research hypotheses, but the way it is worded in the abstract does not indicate or emphasize the significance of the analysis. In other words, the contribution can be highlighted in the validation of the hypotheses and the use of cluster analysis to prove them.

Dissertation notes and recommendations

- Many unacceptable grammatical and stylistic errors are found in the dissertation. Inaccuracies in the names of the National Council for Prices and Reimbursement of Medicinal Products (p. 118, 122), the Bulgarian Association for the Development of Parallel Trade in Medicines (p. 123), and figure titles (fig. 12).

- At the beginning of the dissertation, a list of used abbreviations is missing, which makes it difficult to read the dissertation work.

- When presenting the figures, there is no need to duplicate their title in the graphs themselves.

- For greater representativeness, credibility, and objectivity of the analysis, it is necessary that the number of in-depth interviews be greater than the number of only three interviews. It is not possible to make valuable generalizations based on the opinions of three respondents.

- Based on the notes, I recommend that the author give serious attention to the language and style and to the editorial work before proceeding with future publications.

Questions

The use of qualitative methods of analysis indisputably enriches the study and allows for covering the problem from different points of view. In this regard, what was the strategy and how did you determine the profile and number of respondents who took part in the in-depth interviews?

Evaluation of the abstract and publications

The abstract meets the requirements and reflects in a synthesized form the structure and content of the dissertation work. It is prepared in a volume of 42 pages and includes the following sections: general description of the dissertation, structure and content of the dissertation, summary of the chapters of the dissertation, statement of contributions, conclusion, and list of publications. I accept that the four articles presented, of which three are independent and one collective, successfully popularize the achievements of Ralina Mircheva and meet the scientometric requirements.
Conclusion

Considering the difficulties in obtaining primary information from pharmaceutical companies, I appreciate the efforts and persistence of the doctoral candidate to develop this topic in conditions of confidential information that do not allow for the disclosure of enough details. Therefore, other sources are sought whose information base would be useful for achieving the objectives of the research.

The dissertation examines a current problem of importance for the health and pharmaceutical sectors and would have practical applicability if it contributed to the solution of the identified problems.

The dissertation meets the requirements of the Law on the Development of the Academic Staff in the Republic of Bulgaria, its Rules for Implementation, and the Rules for the Development of the Academic Staff of the University of Economics - Varna. In conclusion, despite the comments, I give a positive assessment and propose to the respected members of the Scientific Jury to award the educational and scientific degree "Doctor" to Ralina Dobrinova Mircheva in the field of higher education 3. Social, economic and legal sciences and professional field 3.8 "Economics".

27 May 2024

Signature: [Signature]

/Assoc.Prof. Elka Atanasova, PhD