

OPINION

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Pursuant to Order № R-109-380/18.09.2025 r. of the Rector of MU "Prof. Parascev Stoyanov" -
Varna

for a dissertation on:

**“CENTRALIZED RECONSTITUTION OF MEDICINAL PRODUCTS FOR
SYSTEMIC TREATMENT OF MALIGNANT
DISEASES IN HOSPITAL PHARMACIES IN BULGARIA – SPECIFICS,
CHALLENGES, AND PERSPECTIVES”**

Author: MPharm. Velina Hristova Grigorova

for the award of the educational and scientific degree "Doctor", in the field of higher education 7.
Health and Sport, professional field 7.3. Pharmacy in the Doctoral Programme “Hospital Pharmacy”,
Scientific supervisors: Prof. Evgeni Grigorov, PhD (Pharmacy) and Prof. Assena Serbezova, DMSc.

The statement was prepared in accordance with the Law on the Academic Staff
Development in the Republic of Bulgaria and the Regulations for its implementation at the
Medical University of Varna.

I. Brief biographical data

Doctoral student Velina Grigorova has completed two higher degrees: a Master’s in Biology from Sofia University “St Kliment Ohridski”, and a Master’s in Pharmacy from the Medical University of Sofia. Continuing to build upon her knowledge and expertise, she has also obtained two healthcare specialisations: *Clinical Pharmacy* and *Hospital Pharmacy*. In 2022, she became the first doctoral student in Bulgaria to enrol in the newly accredited doctoral programme in *Hospital Pharmacy* at the Medical University “Prof. Dr Paraskev Stoyanov” in Varna. Velina Grigorova is a recognised professional in the pharmaceutical field, with over 25 years’ experience in hospital pharmacies within medical institutions. Over the years, she has also held various positions within the professional organisation of master pharmacists (BFU), including serving as its Chair for one year. She was Chair of the Board of the Professional Organisation of Hospital Pharmacists in Bulgaria (POBFB) for two consecutive terms, contributing significantly to the development and establishment of this branch of the pharmaceutical profession. At present, Velina Grigorova is the manager of one of the largest hospital pharmacies in Bulgaria, located at Acibadem City Clinic UMBAL Tokuda in Sofia. She is fluent in English and has working knowledge of Russian.

II. Analysis of the Dissertation

The dissertation of M.Pharm. Velina Grigorova, submitted for review, comprises 139 standard pages and is structured as follows: Introduction; Chapter I – Literature Review; Chapter II – Aim, Objectives, Materials and Methods; Chapter III – Results; Discussion; Conclusion; Contributions; Appendices, and References. The work is illustrated with 54 figures and 10 tables, and the questionnaires are included in the appendices. The bibliography contains 139 references, the majority of which are in Latin script.

III. Assessment of the relevance and significance of the topic

The relevance of the chosen dissertation topic stems from an extremely pressing issue: the rising number of patients with oncological diseases and, in parallel, the growing need to ensure safety when handling cytostatics, as well as the efficient use of resources within the healthcare system. The research assesses the working conditions and level of occupational risk faced by hospital pharmacists, along with their significant role and contribution to clinical practice and therapeutic outcomes. The study provides both a horizontal and vertical analysis of the evolution, current state, future directions and opportunities for improvement in oncological pharmacy and hospital pharmacy services. The data have the potential to contribute to higher-quality, economically efficient, safe and cost-effective preparation, storage and administration of medicines for systemic cancer treatment in Bulgaria.

The literature review demonstrates the in-depth theoretical preparation of the doctoral student, Velina Grigorova. It is based on up-to-date sources and is both thorough and analytical.

The review examines in detail:

- ✓ the nature and classification of medicinal products used for the systemic treatment of malignant diseases;
- ✓ the rationale for the development and introduction of centralised cytostatic preparation, including the conditions required for compounding, staff training, and the procedures applied in Bulgaria.

IV. Assessment of the Aim, Objectives, and Methodology

Based on an extensive review of the literature, the doctoral candidate has defined the aim of the scientific work: to examine and analyse the process of centrally preparing medicinal product solutions for the systemic treatment of malignant diseases within hospital pharmacies in Bulgaria, as well as the training of personnel responsible for undertaking this specialised pharmaceutical activity. Six tasks have been set, each aligned with the stated aim, and the methodology is coherent with these objectives. This study is the first of its kind in Bulgaria and carries considerable scientific and practical value in this field—normatively, organisationally, and in terms of professional practice. The methodology adopted for the study is appropriate and well chosen. A historical review, documentary and statistical analyses were employed, and interviews were conducted in 18 medical institutions across the country that provide treatment for oncological diseases. The study clearly specifies its period and setting, the methodology applied, the inclusion and exclusion criteria, and the procedures for recruiting respondents. I

consider the research to be thorough and to have successfully met the aims and objectives set out in the doctoral thesis.

V. Evaluation of results

Doctoral student Velina Grigorova presents several analyses in her thesis. The first section of the Results Chapter is devoted to an examination of the current regulatory framework and the actual state of hospital pharmacies that carry out the centralised preparation of medicines for the systemic treatment of oncology patients. The information provided is extensive and demonstrates a deep understanding of both the legislation and its practical implementation. The principal conclusion is the absence of centralised oversight of the preparation of medicines used in the systemic treatment of malignant diseases.

The second section synthesises a substantial volume of information regarding medical institutions that provide oncological care in the country—covering the number of hospitals, available bed capacity, ownership structures, funding sources, and geographical distribution. The construction and equipping of an aseptic unit for preparing solutions for the systemic treatment of oncological diseases, as well as ensuring the availability of qualified personnel, represent significant investments for any hospital. The key conclusion here is that a more effective approach could be adopted, enabling more rational planning and utilisation in preparing solutions both for the institution's own patients and for those of other hospitals.

The third part of the study reports on the unusable residues resulting from the preparation of antineoplastic medicines, as submitted to the NHIF for the period 2020–2024. Following an in-depth analysis of dose-calculation methods, the reasons for non-reporting of residues, and data from nine medical institutions, the most important conclusion is that there is considerable potential for meaningful and effective reform in the use of cytostatics, leading to a reduction in public expenditure. This constitutes a valuable analysis for cost reduction, with savings that could be redirected to other activities in the treatment of cancer patients.

The subsequent two sections explore the profile of pharmacists involved in preparing parenteral antitumour solutions, as well as the training provided to teams working in pharmacies with centralised cytostatic preparation. A key conclusion is the absence of academic or specialised training courses, which presents an important opportunity for universities to complement existing training offered by professional and non-governmental organisations. The chapter also includes specific recommendations to state institutions and universities aimed at improving the regulatory framework and training provision. In total, the dissertation presents 14 conclusions.

VI. Evaluation of contributions

The contributions made by the author are extremely useful both in scientific-theoretical and scientific-applied terms, providing solutions for the better management and organization of the centralized dissolution of medicinal products for the systemic treatment of malignant diseases in hospital pharmacies in Bulgaria. The doctoral student Velina Grigorova

demonstrates high expertise and presents real problems in practice, drawing valuable conclusions for the development of the profession and the challenges facing the profession.

VII. Abstract and publications on scientific work

The abstract has been prepared in accordance with the requirements of the Regulations for the Development of the Academic Staff of the Medical University–Varna and accurately reflects the results obtained and the scientific contributions of the dissertation.

Five publications in scientific journals and fourteen conference participations related to the topic of the dissertation are presented. In almost all of the articles, the doctoral student is listed as the first author, which demonstrates her direct involvement in the development, discussion, and presentation of the findings. Furthermore, one of the articles has been published in an international journal with an impact factor, which serves as clear evidence of the significance of the research conducted. I also identified three Scopus citations of an article arising from Velina Grigorova’s doctoral studies.

The values of the main groups of indicators are presented in the table:

Group of indicators	Regulations for the implementation of the Law	Regulations for the development of the academic staff at MU-Varna	MPharm. Velina Grigorova
A (A)	50	50	50
D (Г)	30	30 (2 publications, of which 1 in journals referenced in Scopus/Web of science)	59,5 Total 5 1 article (Scopus)
Total points			109,5

In conclusion, I consider that the dissertation submitted by Velina Grigorova, entitled **“CENTRALIZED RECONSTITUTION OF MEDICINAL PRODUCTS FOR SYSTEMIC TREATMENT OF MALIGNANT DISEASES IN HOSPITAL PHARMACIES IN BULGARIA – SPECIFICS, CHALLENGES, AND PERSPECTIVES”** fully meets the requirements of the Act on the Development of Academic Staff and the Regulations of MU–Varna for the award of the educational and scientific degree “Doctor”, in terms of its relevance, precision, and scope.

The dissertation possesses scientific–educational, scientific–applied, and methodological value. The recommendations put forward are directed at specific institutions, which makes them particularly valuable from a practical and applied perspective.

On the basis of the above, I strongly recommend that the scientific jury confer the educational and scientific degree “Doctor” upon Velina Grigorova.

Nov 12th, 2025

Prof. Antoniya Yanakieva, I

Заличено на основание чл. 5,
§1, б. „В“ от Регламент (ЕС)
2016/679