

REVIEW

From Prof. Dr. Emil Gachev, MD

For the competition for associate professor at the Medical College of the Thracian University in the scientific specialty "Pharmacoeconomics and Pharmaceutical Regulation"; field of higher education 7. Healthcare and sports, professional field 7.3. Pharmacy, scientific specialty "Pharmacoeconomics and Pharmaceutical Regulation" for the needs of the specialty "Assistant Pharmacist" - one in 0.5 staff,

(State Gazette, issue 61 / 10.07.2020)

Documents on the procedure

By Order of the Rector of the Thracian University I was selected as a member of the scientific jury in a competition for associate professor in the scientific specialty "Pharmacoeconomics and Pharmaceutical Regulation" for the purposes of the Medical college at the University, announced in SG 61 / 10.07.2020 and at the first meeting of the scientific jury I was chosen as a reviewer of the competition.

Two candidates are admitted to the competition - Master Pharmacist Nikolay Gerasimov, Ph.D. and Master Pharmacist Anna Mihailova, Ph.D.

Master Pharmacist Nikolay Gerasimov has presented all the necessary documents for the procedure (35 in total), and Master Pharmacist Anna Mihailova has presented 28 documents without the declarations of co-authorship of the publications and distribution protocol for co-authorship in one monograph.

Biographical data for the candidates

Master Pharmacist **Nikolay Gerasimov, Ph.D.** graduated in pharmacy in 1994, in 2001 he acquired a degree in "Organization and Economics of Distribution and Pharmacy Practice", and in 2016 he acquired a ONS "Doctor" in Pharmacoeconomics and Pharmaceutical Regulation. Nikolay Gerasimov has been working consistently and entirely as a pharmacist since 1994 - in a hospital pharmacy, a pharmacy for public services and as a part-time lecturer at the Faculty of Pharmacy of the Medical University of Varna.

Master Pharmacist **Anna Mihailova, PhD** graduated with a bachelor's degree in rehabilitation in 1995, in administrative and health management in 1998, health care in 2000, a master's degree in public health and health management in 2004 and a master's degree in pharmacy in 2008. In 2018 she obtained a PhD in Pharmacoeconomics and Pharmaceutical Regulation at the Medical University of Plovdiv. For the purposes of this competition I consider the professional development, specializations, teaching and research activities in connection with the acquisition of the master's degree and doctoral dissertation in Professional field 7.3. Pharmacy. The acquired postgraduate specialty is in connection with ONS Bachelor and is in "Medical Pedagogy", which is why I believe that it does not concern the competition for associate professor.

Anna Mihailova has been working as a manager of a pharmacy for population service and since 2008 as a lecturer to assistant pharmacists at the Medical College Plovdiv.

Dissertations for the award of ONS "Doctor"

Nikolay Gerasimov defends ONS doctor with the topic: "Medical devices in the pharmaceutical nomenclature - legislative and social aspects in their provision in Bulgaria."

Anna Mihailova defends ONS doctor with the topic "Epidemiological and pharmaco-economic study of corticosteroid prophylaxis of hyaline membrane disease in premature infants."

The two doctoral dissertations have been evaluated according to other procedures, which is why I do not evaluate them, but only note that both are in the professional field 7.3 Pharmacy and doctoral program "Pharmacoeconomics and Pharmaceutical Regulation".

According to this indicator, both candidates have 50 points.

Monographic works

Nikolay Mihailov presented a monograph on "Medical devices - legislation and economic analysis" in 206 pages (106 pages above the required volume). The introduction to the monograph addresses issues such as definitions of concepts such as medical technology, medical device, MI in vitro, medical equipment for diagnostic imaging and e-health. The nomenclature of the Ministry of Economy and their role and place in the system of healthcare and health care are considered. A brief economic analysis of the role of the European technology medical industry is made - direct employment in the sector, value added per employee, number of companies based in Europe, analysis of SMEs in MedTech, a comparative economic analysis of the costs of MI and total costs of health from GDP is made, the markets of the Ministry of Economy of the individual European countries, the trade balance, the high share of innovations and patents in the sector and the high level of investments in R&D activity are considered. This section uses literature sources from the period 2018 - 2020. The monograph can be considered as a continuation of the research and problems considered by the candidate Gerasimov in the doctoral dissertation in February 2016, because for almost five years there have been significant changes in the legal framework. for MI European Union adopted in the period 1990 - 2007. The monograph provides an in-depth legal analysis of the new legislative framework - Regulation MI 2017/745 / EU, which enters into force in May 2020. The direct applicability of the two Regulations in the medical legislation of the EU Member States creates new rights and obligations for all economic operators, notified bodies, medical professionals, consumers and patients, regulatory competent authorities at European and national level, and a smooth transition from Directives to Regulations must be ensured. . The new aspects that are analyzed in the monograph are achieving a higher level of clinical safety, creating equal access to the market, defining new NOs, traceability of the supply chain by introducing unique identification - UDI, CE marking, building NANDO - an electronic system to the EC, a change in classification with the introduction of a pre-market consultation procedure for

high-risk MI, strengthening the requirements for clinical evaluation and performance evaluation with increased criteria and the creation of an EUDAMED database that will provide information to patients, medical professionals and economic operators. The monograph examines the challenges facing European legislation and the consequences for the MI market in the context of the COVID 19 pandemic, as a legislative analysis of the EC documents from 2020 in connection with the health crisis, overcoming the deficit of MI and PPE and ensuring the access of patients and medical professionals to them as in the market surveillance procedures by the competent state authorities must give priority to non-compliant MI, which may pose risks to the health and safety of their users.

Anna Mihailova presented 9 pages of a monograph on "Good Pharmaceutical Practice in the Training of Assistant Pharmacists". From the attached content it is evident that the monograph is in a volume of 187 pages (87 pages above the required volume). In the presentation of the monograph it is written that it is an author's course in the discipline DFP, which raises the question of whether it is a textbook or a monograph, but given the two reviews I accept the work as the required monograph. The work contains three main sections dedicated to good practices in pharmacy, aspects of professional development of assistant pharmacists, assessment of training in the elective discipline for which the course is intended. The first part, according to the introduction to the paper is more theoretical and includes the main developments in connection with good pharmaceutical, pharmacy, production and distribution practice, as well as their relationship with ISO standards. Also included is the role of pharmacists in health promotion and drug safety monitoring, which are important in view of the current pandemic situation. The second part of the work, according to the description, has the character of a more of a textbook that presents teaching methods, and the third part is supposed to be the author's own research. Unfortunately, the candidate did not submit the entire monograph, which is puzzling to me, as the role of the reviewer is to assess whether the work meets the requirements of the Law on Monographic Work, to monitor whether there are own studies and others. All the so-called "manuals" in the list of documents are only title pages and content without full text. It is impossible for me to appreciate the originality of the monographic work.

In addition, in the description of the documents, the candidate states that she participates with a part of a monograph on "Health and economic assessment of the costs of premature babies with respiratory complications." For this work is not presented the full scope of work and no separation protocol for co-authorship, which is why I don't consider it.

I accept that according to this indicator both candidates have the required 100 points, but I remain with reservations about the candidate Anna Mihailova due to the lack of the full text of the monograph. I do not appreciate the joint monograph due to the lack of a separation protocol.

Scientific publications and activities

Nikolay Gerasimov participates in the competition with 16 publications, of which 14 were published in full text, and two were submitted for publication and I do not review them. All publications are on the topic of the competition "Pharmacoeconomics and Pharmaceutical Regulation". According to reports submitted by CMB and NACID, an extract

from the public register **9 of the publications are in journals referenced in SKOPUS, 5 in non-refereed journals and there are no publications in a journal with an impact factor according to Thompson Reuther (Clarivate). The total sum of the points from the mentioned publications is 277.80 points.** The one-way development of the candidate in the field of medical devices is impressive, in which 8 of the publications are, and the rest are in the field of pharmacoeconomic studies of the therapy of socially significant diseases. In the field of medical devices, the main contributions of the applicant can definitely be attributed, and more precisely in the study of the legislation, the safety of the market characteristics of the medical devices.

To the scientific activities I also include the participation in congresses and conferences - a total of 5 outside the doctoral dissertation of Nikolai Gerasimov, as well as participation in a **research project** on "Assessment of the safety of hernia sheets by studying their mechanical compatibility with tissues and quality of life of patients."

Nikolay Gerasimov has presented evidence for 4 citations in referenced and indexed in world-famous databases and 9 citations in other foreign databases, as well as 6 citations in Bulgarian sources, as shown by a reference from CMB. **(total number of points 135).**

As an additional activity of the candidate I consider the data presented by Nikolay Gerasimov for implementation of standard operative procedures in a pharmacy for work with narcotic substances and for dispensing of medicinal products paid by the NHIF.

Anna Mihailova has presented 41 publications in the competition. Three of them are from the doctoral dissertation, due to which they cannot be included in the documentation, but the candidate also presents them in this competition (publications № I.1, I.2, IV.2). These publications are excluded from this review. According to a report submitted by the Central Library of TrU, **9 of the publications are in refereed editions in Scopus with impact rank, there are no publications with impact factor according to Thompson Reuther (Clarivate),** despite the fact that the candidate believes that 6 of the publications have impact factor. As I have already mentioned for this competition, I have reviewed only publications that are in the doctoral program "Pharmacoeconomics and Pharmaceutical Regulation". These are publications № III.1., III.8, III.10., III.11., III.12, IV.2, IV.4., IV.17., IV.19, V.1 to V.6 inclusive, V.8., VI.1., VI.3, VI.4, VI.5, VI.8 and VI.9 of the Annex List of scientific papers. **The total number of points from the above publications is 218.66 points. The development of the candidate in the field of pharmacoeconomics and pharmaceutical regulation is very diverse and there can be no unified scientific orientation.**

At the same time, I cannot fail to note the predominant development of the candidate in the field of rehabilitation and physiotherapy, which corresponds to her bachelor's degree, and these publications probably built scientific thinking without contributing to the development of pharmacoeconomics and pharmaceutical regulation. At the same time, I cannot fail to mention some publications in which I do not understand the involvement of a pharmacist or physiotherapist, such as **IV.8** Buttigieg GG, Mihaylova AA, Uchikova EH, A 50 year old myth: The relationship of intra- partum cardio-tocographic monitoring to cerebral palsy at clinical and medico-legal level. Knowledge International Journal, 2019, Vol.32.2, p.221-229, as well as publication **IV.11.** Dzhambazov K, Zheliazkov H, Stoyanov G, Rouev P, Traykova N, Mihaylova A, Petleshkova P, Markov S, Endonasal endoscopic sinus surgery with rhinobasis resection due to esthesioneuroblastoma: case report. Biomedical Research 2019; 30 (2):

248-252, DOI: 10.4066 / biomedicalresearch.30-19-024; **IV.13.** Petleshkova P., Krasteva M., Gencheva D., Anesteva-Ivanova N., Grozdanova L., Parahuleva N., Mihaylova A. Biomedical Research 2019; 30 (2): 362-365, DOI: 10.4066 / biomedicalresearch.30-19-112. I understand that Ms. Mihaylova has diverse interests, but she has hardly participated in the surgical procedures described in the second publication or in cardiovascular monitoring and detection of cardiac defects in newborns described in the first and third publications.

The participations in congresses and conferences of Anna Mihailova are 20 on the topic of the competition.

Anna Mihailova also participates in 4 textbooks, all of which are on the topic of the competition and according to the rules for co-authorship form another 26.6 points.

According to the presented reference, 3 citations were found in refereed scientific journals and 15 in non-refereed scientific journals, of which 3 citations in monographs and 2 citations in scientific theses of the candidate (**155 points**).

The research project in which **Anna Mihailova** participates is one - "Application of immunostimulatory methods to improve the quality of life in children from 4 to 7 years of age", funded by MU Plovdiv. (**15 points**). The candidate was a mentor to three students on a project from the Structural Program of the Ministry of Education and Science for students and internships, but I do not think that this is a research project, but only an additional academic activity. This mentoring is classified as a Guide to State Pre-Diploma Internship for 5th year students in 20018 and 2019 (**45 points**)

Both candidates participate in prestigious scientific organizations - international and national.

Teaching activity of the candidates

Nikolay Gerasimov participates in teaching pharmacists with a workload of 150 hours for the academic year 2012-2013, as well as specialists for pre-diploma internship in pharmacy in the academic year 2018-2019.

According to the information provided by the Medical Center Plovdiv, **Anna Mihailova** teaches assistant pharmacists with 100 hours of teaching load per year for exercises, 435 hours of practical training, 55 hours of lectures, 208 hours of participation in exams. Two additional agreements for academic mentoring under a project of the Ministry of Education and Science for student practice are also presented. To the teaching activity I also refer the participation in four textbooks, for which again only the initial pages, content and final pages are presented. The textbooks are on the topic of the competition and the training of assistant pharmacists.

As a study load, I believe that both candidates have the necessary experience to conduct training as assistant pharmacists at the Medical College of the Thracian University.

Fulfillment of the minimum state requirements

When summarizing the achievements of the candidates, according to the requirements of the Regulations for development of the academic staff at RDASRB, the ranking is as follows.

GROUP OF INDICATORS	ASSOCIATE ASSISTANT	REQUIRED POINTS	NIKOLAI GERASIMOV	ANNA MIHAYLOVA
A (INDICATOR 1)	Dissertation work for awarding an educational and scientific degree doctor	50p	50p	50p
C. (INDICATOR 2)	Habilitation work - Monograph	100p	100p	100p
D. (INDICATORS 5 TO 9)	7. Publications in scientific peer-reviewed and indexed journals in global databases of scientific information 8. Publications published in non-refereed journals with scientific review	200p	277.8p	245.26p
E. (INDICATORS 10 TO 12)	10. Citation in scientific journals, referenced and indexed in world-famous databases 12. Cited in non-refereed journals with scientific review	50p	135p	155p
F. (INDICATORS 13 TO THE END)	15. Acquired medical specialty; 22. Management of state pre-diploma		60p	45p

	internship of students			
Total		400	662.80	595.26

Conclusion

Given the final ranking of the candidates, as well as the full compliance of scientific development with the guidelines of the competition, I recommend the esteemed scientific jury to choose Nikolay Mihailov Gerasimov, PhD in the academic position of "Associate Professor" in Pharmacoeconomics and Pharmaceutical Regulation; field of higher education 7. Healthcare and sports, professional field 7.3. Pharmacy, scientific specialty "Pharmacoeconomics and Pharmaceutical Regulation" for the needs of the specialty "Assistant Pharmacist" - one in 0.5 staff, at the Medical College, Thracian University, Stara Zagora (State Gazette, issue 61 / 10.07.2020).

12/8/2020

Reviewer:

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