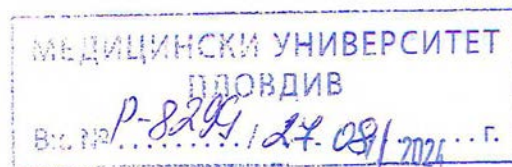


REVIEW



on a competition for awarding of Academic Position (AP) "Professor" in the "Health and Sports" field of higher education of professional sphere "Pharmacy", announced in SG No. 47/04.06.2024 on the scientific specialty "Pharmacoeconomics and pharmaceutical regulation" for the needs of "Organization and economics of pharmacy" department at the Faculty of Pharmacy of the Medical University - Plovdiv.

Only one candidate was admitted to the competition: Assoc. Prof. Stanislav Radoslavov Georgiev, MPharm, PhD

Reviewer: Assoc. Prof. Kalin Ivanov, MPharm, PhD; Scientific specialty "Pharmaceutical Chemistry", Head of the Department of Pharmacognosy and Pharmaceutical Chemistry, Dean of the Faculty of Pharmacy at the Medical University - Plovdiv.

Pursuant to the Order of the Rector of Medical University (MU) - Plovdiv No. P-20-2650 dated 07 August 2024, I was provided with the documents of the candidate Assoc. Prof. Stanislav Radoslavov Georgiev, MPharm, PhD. The competition materials are prepared in accordance with Art. 4 and 26 of the Law on the Development of the Academic Staff in the Republic of Bulgaria (LDASRB), the Regulations and rules for its implementation and the Regulations for the organization and operation of MU-Plovdiv. The review of the provided documentation gives me the right to assume that the procedure for starting and announcement of the competition has been followed.

1. Curriculum vitae particulars, career development and employment history

Assoc. Prof. Stanislav Radoslavov Georgiev, MPharm, PhD acquired Educational Qualification Degree "Pharmacy" in 1999 at the Faculty of Pharmacy of the Medical University - Sofia. In the same year, he began his professional development as a magister pharmacist in a wholesale warehouse "Gloria International Limited EOOD". Since 2000, he was employed as a medical representative in a "Glaxo Smith Klein" sales office. From 2001 to 2007, he was a part-time PhD student at the "Organization and Economics of Pharmacy" department of the Medical University - Sofia, Faculty of Pharmacy. From 2004 to 2006, he worked as a medical representative at the "Boehringer Ingelheim" sales office. In 2007, he obtained the educational scientific degree "PhD" by defending a dissertation on the topic "Study of the possibilities for the implementation of pharmaceutical care in pharmacy practice" before the Higher Attestation Commission.

He obtained specialties in "Organization and Economics of Distribution and Pharmacy Practice" (2012, Faculty of Pharmacy, MU – Sofia) and "Hospital Pharmacy" (2020, FP, MU – Sofia). In 2008, after a competition, he took the position of AP "assistant" at MU - Plovdiv. In 2010 he gained the position of a chief assistant professor, and in 2012 he was appointed as an associate professor in the Department of Pharmaceutical Sciences. In the period 2015 - 2019 he held the position of deputy dean for Educational Activities in the FP of MU - Plovdiv. He is a member of: the Expert Council on Activities in Organization and Economy, Drug Technology and Hospital Pharmacy at the Minister of Health; The Ethics Committee of the Board of Directors of the Bulgarian Pharmaceutical Union; The expert council on retail trade at the Executive Drug Agency (EDA); The specialized commission for herbal medicinal products to the Executive Director of EDA; The specialized commission for determining the affiliation of medicinal products to the Executive Director of EDA; The Bulgarian Scientific Society of

Pharmacy; The Faculty Council of the Faculty of Pharmacy of MU-Plovdiv; State examination boards.

2. Characteristics and assessment of the candidate's scientific and research activities

The documentation of Assoc. Prof. Stanislav Georgiev, MPharm, PhD was completed according to the requirements of the Regulations for Academic Development of MU-Plovdiv. It is supported by the necessary evidence of scientific publication activity. In the current competition, the candidate participated with 41 scientific publications, of which 23 were in referenced journals and 18 were in non-referenced journals, a dissertation for the acquisition of the EQD "Doctor", habilitation thesis/monograph - 1 book and participation with 2 chapters in collective monographs, published university textbooks – 2 books, published university textbooks – 9 books. The presented scientific works, according to the requirements of the procedure, were published after receiving the AP "associate professor". A detailed abstract of the available papers is presented, as well as the original articles. Attached is a table of compliance with the scientometric requirements of MU-Plovdiv University for the appointment of AP "**Professor**" and the evidence presented by the applicant.

GROUP	INDICES	VALUE	ASSOC. PROF.	PROFESSOR	Assoc. Prof. Stanislav Georgiev,
A	1. Dissertation work for the award of the educational and	50	50	50	<u>50</u> points
B	2. Dissertation work for the award of the scientific degree "DSc"	100			-
C	3. Habilitation thesis - monograph	100	100	100	<u>100</u> points
	4. Habilitation work - scientific publications (not less than 10) in publications that are referenced and indexed in world-famous databases with scientific	60/n per each publication			-

GROUP	INDICES	VALUE	ASSOC. PROF.	PROFESSOR	Assoc. Prof. Stanislav Georgiev,
D	5. Published monograph that is not presented as the main habilitation thesis	100	210 points 10 journal articles referenced in Scopus and/or Web of Science, including 6 articles with IF	300 points 20 articles, of which 15 in journals referenced in Scopus and/or Web of Science, including 8 articles with IF	<u>100</u> points
	6. A published book based on a defended dissertation for the award of an educational and scientific degree "Doctor" or for the award of a scientific	40			
	7. Publications and reports published in scientific publications, referenced and indexed in globally recognized scientific databases	60/n or distributed pro rata based on contribution protocol			<u>230,7</u> points 23 publications 9 with IF
	8. Publications and reports published in non-referenced peer-reviewed journals or published in edited collective volumes	30/n distributed pro rata based on contribution protocol			<u>106,10</u> points 18 publications
	9. Published chapter of a collective monograph	20/n			<u>20</u> points
F.	10. Citations or reviews in scientific publications referenced and indexed in world-renowned databases of scientific information or in monographs and collective volumes	15	300 points 12 citations in journals referenced in Scopus and/or Web of Science	500 points 12 citations in journals referenced in Scopus and/or Web of Science	<u>720</u> points 48 citations

GROUP	INDICES	VALUE	ASSOC. PROF.	PROFESSOR	Assoc. Prof. Stanislav Georgiev,
	11. Citations in peer-reviewed monographs and collective volumes	10			<u>30</u> points 3 citations
	12. Citations or reviews in non-refereed peer-reviewed journals	5			<u>425</u> points 85 citations
F	13. Awarded scientific degree "PhD"	40	50 points - 2 scientific projects (including intra-university projects (IUP)) - acquired specialty	150 points - 2 students defended successfully a PhD Thesis - 1 scientific project - 1 manual / handbook	-
	14. Supervisor of a successfully defended PhD student (n is the number of co-supervisors of the	40/n			<u>160</u> points
	15. Acquired medical specialty	40			<u>80</u> points
	16. Participation in a national scientific or educational project	15			<u>30</u> points
	17. Participation in an international scientific or educational project	20			-
	18. Management of a national scientific or educational project	30			<u>30</u> points
	19. Management of a international scientific or educational project	40			-

GROUP	INDICES	VALUE	ASSOC. PROF.	PROFESSOR	Assoc. Prof. Stanislav Georgiev,
	20. A published university manual or a textbook that is used on	40/n			<u>44,7</u> points 9 manuals
	21. A published university textbook or a textbook that is used on the school network	20/n			<u>5</u> points 2 textbooks
	22. Training of interns, post-graduate and PhD students (seminars and practical classes)	30			<u>300</u> points 10 post-graduate students
	Teaching activity:				
G	Teaching load (lectures and exercises):		360 points (for the last two years 2 years X 0.5 points/	360 points (for the last two years 2 years X 1 point/hour)	<u>940</u> points
	Academic position:		200 points (chief assistant professor - 100 p. per 1 year.)	200 points (assoc. professor - 100 p. per 1 year)	<u>1100</u> points
	TOTAL:		1270	1660	<u>4471.5</u> points

I accept the presented candidate's self-evaluation and the supporting evidence attached to it, according to the quantitative scientometric indicators. The coverage requirements of the national minimum criteria and those of MU-Plovdiv for the acquisition of JSC "Professor" have been met. A reference is presented for 136 citations of the candidate's works, of which 48 in Scopus. A Scopus reference based on the number of documents and citations of the applicant determines a Hirsch index of 4.

3. Scientific contributions

The scientific contributions as presented in the reference are focused on drug interactions, self-management, pharmaceutical care, pharmacoeconomics and regulatory approaches to authorization of drugs for use, training of pharmacy students and comply with the requirements

of the announced competition. I accept the attached author's reference for the contributions of the scientific developments, reflected in the subject of the scientific works. Main thematic directions:

MAJOR EMPHASIZED SCIENTIFIC TOPICS:

I. DRUG INTERACTIONS AND ADVERSE DRUG REACTIONS (item 10 Monograph; 13.6; 13.15)

The administration of different medicinal products and polypharmacy creates conditions for various drug interactions, some of which may be associated with an increased risk of toxicity and adverse effects. Medicinal products interact with each other, with foods, nutritional supplements or phytopharmaceuticals. Possible interactions may cause undesired effects. In recent years, the possibilities for intensive *in vitro* and *in vivo* studies have expanded, through which the mechanisms of beneficial and undesirable interactions are revealed. This knowledge makes possible the development of combined therapeutic strategies. The study evaluates patients' awareness of drug use (administration, adherence to drug therapy) and identifies possible drug-related problems in patients using 5 or more drugs on Bulgarian territory. The results show that it is necessary to introduce the Medication Review service in Bulgarian pharmaceutical practice. This will create opportunities to promote the role of pharmacists in the dispensing of medicinal products, help reduce medication-related problems and increase treatment effectiveness and adherence to medical therapy. Since 2012, in line with changes in European legislation, the Executive Drug Agency has been receiving reports of adverse drug reactions (ADRs) directly from patients, as well as from healthcare professionals and marketing authorization holders. Reports of ADRs from patients and consumers have different characteristics than those submitted by healthcare professionals. The analysis of the database showed a stable level of patient reporting with a steady growth trend each year. Bulgaria follows global trends for a high number of reports of understudied ADRs that meet the criteria for serious concern. It was concluded that current pharmacovigilance methods were not sufficiently sensitive for specific groups of drugs. The results confirmed the importance of reporting as a valuable source of information on adverse drug reactions. Attention was drawn to the lack of more sensitive methods for evaluating the safety of drugs in specific pharmacological groups. Maintaining a user-friendly ADR reporting system and innovative evaluation algorithms should be the future directions for the development of post-marketing surveillance.

II. PHARMACEUTICAL REGULATION

1. Changes in the registration regime of dietary supplements (13.16)

Data provided by the European Commission showed that the market for dietary supplements (DS) was growing continuously. The main regulations regarding DS in the European Union and in Bulgaria have been studied. The lack of strict control over DS represents a serious risk, as low-quality products with poor production control can be distributed in EU member states. The Bulgarian national legislation incorporates 6 regulations with different legal force, which regulate the market supply of healthy and safe DS. The European Parliament and the Council should undertake a number of legislative initiatives in the field of production and control, with the aim of establishing stricter quality and safety criteria in future strategies related to those products.

2. Crisis management and counteraction against some infectious diseases. (14.2; 13.3)

The European Health Emergency Preparedness and Response Authority (HERA) is engaged in analyzing the actions of the European Commission. HERA collects information and predicts threats and potential health crises. A system is being established to ensure the necessary capacity to assist EU member states in limiting the spread of certain infectious diseases. The emphasis is on the importance of cooperation between health authorities at different levels in the counteraction against infectious diseases, as well as against serious cross-border health threats. Specific medicinal products and vaccines provided to Member States through the mechanism of Joint Procurement of Medical Countermeasures were examined, tracing the overall effect: from access to the relevant medicines to improving public health. Data from national and European sources were analyzed, including data on the availability of the medicinal product Veklury in the countries of the European Union participating in the agreement. According to those data, access to appropriate medicines plays a key role in improving patient health by reducing disability and mortality rates, as well as overall health care costs. According to the study, HERA plays an important role in improving public health in the European Union. The Joint Procurement Agreement (JPA) facilitates Member States' access to safe and effective medicines, vaccines and medical devices. Additional initiatives to promote research and development of medical countermeasures and technologies will also help address cross-border health threats. In emergencies and global threats to public health, Member States first choose the JPA in the need for rapid responses by the EU in their activities against (future) epidemics/pandemics. Actions taken by the EC through HERA to help EU Member States restrict the spread of MPOX (an infectious disease caused by the monkeypox virus) are reviewed and analyzed. Compliance and challenges in purchasing pharmaceuticals and vaccines that have not been approved for use within the European Union are discussed. The potential new regulatory challenges facing Bulgaria, in the event of the need for drugs to treat smallpox are highlighted. Emphasis is placed on the need for cooperation between health authorities at different levels in the actions against infectious diseases in order to contribute to reducing the spread of infectious diseases.

III. THE ROLE, APPLICATION AND SIDE EFFECTS OF DIETARY SUPPLEMENTS

1. Therapeutic effect, advantages, regulation (13.16; 14.11)

In recent years, there has been an increased interest in DS. A number of factors contribute to the sustained growth of the DS market: massive advertising, an increased number of commercial facilities offering DS (stores, pharmacies, drugstores, specialized stores for sports supplementation), as well as Internet sales. On the other hand, the legislation allows them to reach the end user quickly. The procedure in most countries is simplified incorporating minimal requirements regarding the official documentation. This is also a reason for the uncontrolled growth of online trade with these products from sites non-regulated by EDA. They are often considered safe by consumers because of their role in supplementing a normal diet. The overview of DS regulations revealed that there was a real risk of distribution of DS of suspicious composition, as well as inadequate production control. This problem provoked the EU to take a number of legislative initiatives in the field of production and control of DS. The national regulation adheres to the requirements of international legislation in this field. However, quality and quantity control of DS is not mandatory either before or after marketing. The conducted research aimed to survey which were the best-selling DS categories in Bulgarian pharmacies. The research covered 820 pharmacies from all over the country. The leading category of dietary supplements was found to be "Immune and Digestive Health" (41.5%). The second place was for "Bone and joint health" (12.9%). The "Urology" category (consisting mainly of plant extracts) covered about 7.9%. The dietary supplements from the "Urology" category were not only

recommended by pharmacists, but were also often prescribed by medical doctors to improve the treatment of kidney stone disease, for the prevention of other pathological conditions or for recurrent infections. The Sports Supplements category was around 4.9%. Dietary supplements in the "Weight loss" category did not occupy leading positions (only 3%). According to pharmacists, the users of this category were mostly women. The results obtained showed that most consumers considered the dietary supplements completely safe.

2. Undeclared ingredients in dietary supplements and their positioning on the market (13.8; 13.5; 13.18, 13.19, 14.15)

Qualitative and quantitative control of DS before and after the production process is not mandatory, unlike that of medicinal products. This is the main reason that has led to alarming reports by many researchers about the presence of undeclared ingredients found in their composition. The lack of mandatory analytical control and the liberal regulatory policy for DS can lead to the presence of intentionally undeclared ingredients, accidental contamination in the production process, fake products. In Bulgaria, as in most countries of the world, obesity is a serious health problem. A healthy diet and regular exercise have been proven to be the main factors in weight reduction. A number of DS can be found on social networks claiming to have a quick effect, without side reactions. The results of a study of 10 DS for weight loss showed that 20% of the tested samples contain a banned, undeclared molecule. That DS is freely sold in the market. The results of the laboratory tests showed that the manufacturer was deliberately deceiving about the safety of the product. When the patient does not suspect the presence of a medicinal substance in DS, he/she cannot expect the side effects and contraindications. The results of a study of 20 DS for the "treatment" of erectile dysfunction aiming to establish the presence/absence of sildenafil, tadalafil and vardenafil, showed that 14 of them contained sildenafil. Professional athletes are exposed to daily and intense physical overloads. The purpose of athletes taking DS is to reduce fat and increase muscle mass, simultaneously improving endurance, as well as to stimulate the recovery process during training. The results of the investigated 23 DS used by athletes showed that manufacturers often added undeclared medicinal substances with proven effectiveness, but also with many side effects and contraindications. Most often they used testosterone and anabolic-androgenic steroids (AAC). In 12 of the examined samples, there were undeclared molecules - methandienone, methyltestosterone, oxandrolone, stanozolol, methenolone, boldenone and androstenolone, etc. On the labels of all 23 studied DS, it was stated that the products did not cause side effects, as well as that there was no age limit. All available anabolic steroids in the composition of the studied DS are banned by the World Anti-Doping Agency. Apart from athletes' health consequences, the intake of such DS also poses a risk for their sports career.

IV. THE NEED FOR "NEW" TRAINING AMONG ADOLESCENTS IN BULGARIA AND PREVENTION OF DRUG USE (14.1)

The use of nitrous oxide (aka laughing gas, paradise gas, etc.) for fun is becoming more and more popular among young people in Bulgaria. Specialized trainings were conducted for pedagogical specialists and adolescents in schools in Bulgaria, providing theoretical knowledge about the psychoactive substance nitrous oxide and the consequences of its use. Special attention has been paid to the fact that the distribution of bottles of nitrogen oxide is carried out freely in the commercial network and the Internet in the form of an electronic cigarette, which constitutes a severe violation due to the concealment of the dangerous substance. Recommendations have been made to restrict the intake in order to maintain good physical and mental health.

V. PHARMACEUTICAL CARE AND PATIENT COUNSELING (point 11 Monograph; 13.7; 13.9)

According to the WHO and International Federation of Pharmacists (FIP) recommendations, pharmaceutical care is a standard for the implementation of pharmaceutical care, in which not only pharmacists, but also other health professionals, accept the professional responsibility and role of the pharmacist for the safe and effective drug therapy of each individual patient. They aim at responsible provision of drug therapy to achieve certain results that not only extend life expectancy, but also improve its quality. In many cases, pharmacists are the health professionals that are most accessible to the population. The COVID-19 pandemic has also outlined this fact. The possibilities of the pharmacist to improve the results for the patient belong with two large groups:

- Participation in programs to improve prescribing.
- Participation in therapy monitoring and therapeutic management_ Participation in therapy monitoring and therapeutic management.

Bulgarian pharmacists generally have a positive attitude towards the provision of pharmaceutical care for children and are available to advise their parents on childhood immunity control. Despite the presence of some barriers, pharmacists demonstrate a high degree of responsibility in providing care and consultation and are willing to increase knowledge and skills in this area through postgraduate training and specialization. 93.7% of respondents considered pharmaceutical care to be the pharmacist's top priority and responsibility when it comes to children. 97.5% agree/strongly agreed with the statement that the provision of pharmaceutical care will improve children's health and their parents' awareness. 84.8% of respondents reported agreeing/strongly agreeing that preventing, detecting, and resolving problems related to children's health and drug therapy is an important responsibility of the pharmacist. According to 72.2% of pharmacists, the main obstacles to the effective provision of pharmaceutical care for children were the lack of additional training and the lack of payment for the service in pharmacies, followed by the lack of time as the main barrier (70.8%). The lack of a separate place for consultation was an obstacle for 62% of the respondents, and for 65.8% a significant obstacle for effective consultation was the lack of access to the child's medical documentation or electronic file. In the pharmaceutical sector in Bulgaria, there is no generally accepted approach to the provision of pharmacy services and no possibility to compare data and results of satisfaction surveys. The intense and growing competition, the heterogeneous structure and the volume of the provided services and activities of the pharmacies impose the need to establish methodology and possibilities for conducting analyzes and comparisons. Customers' satisfaction in the survey was outlined as high, but there was a clear need for additional services to be provided. The results showed that there was a positive attitude towards expanding pharmacy activities and strengthening and elevating the pharmacist's role as a healthcare provider. Such studies using a uniform methodology would be useful for management and regulatory decision-making and should be conducted regularly.

4. Scientific Research Projects.

The presented documents evidence that Assoc. Prof. Mag. Pharm. Stanislav Georgiev, PhD has participated in the following projects:

1. National projects:

- № 4 / 2021 on "Survey on antibiotics self-medication knowledge, attitude and practices" funded by the Medical University – Pleven – member of research team.

2. IUP at Medical University - Plovdiv:

- № СДП-06 / 2016 on “Survey of social and economic aspects of treatment of diabetes mellitus in pregnant women” - project manager.
- № HO-07 / 2020 on “Implementation of immunostimulating methods to improve life quality in children aged 4 – 7” – member of the project team.

5. Teaching engagements.

The reports presented by the Education and Training Activities Department and the Post-graduate Training Department of Medical University – Plovdiv outline clearly the horary of Assoc. Prof. Stanislav Georgiev, MPharm, PhD. The candidate is supervisor of 5 successfully defended PhD students and supervisor of 10 post-graduate students specializing in "Organization and Economics of Distribution and Pharmacy Practice".

6. Conclusion.

Based on the analysis of the scientific work and contributions presented by Assoc. Prof. Stanislav Georgiev, MPharm, PhD, I believe that the candidate meets the national and institutional requirements for being awarded with AP "Professor". The scientometric indicators of the candidate by some of the criteria exceed the mandatory requirements. The candidate's scientific achievements have been realized both individually and as member of authors' teams. The scientific and expert activity of Assoc. Prof. Stanislav Georgiev, MPharm, PhD, as well as his work with students, post-graduate and PhD students characterize him as a recognizable specialist and demonstrate his dedication to scientific and educational activities. Based on all of the above, I believe that the only candidate in the announced competition, with the indicators and the value of his scientific production, meets the requirements of LDASRB and the rules for its implementation, as well as the Rules for Academic Development of Medical University-Plovdiv. **I vote positively and recommend to the members of the respected Scientific Jury to vote positively for awarding AP "Professor" to Assoc. Prof. Stanislav Georgiev, MPharm, PhD in the scientific specialty "Pharmacoeconomics and pharmaceutical regulation".**

22.08.2024

Reviewer:


Заличено на основание
Чл.5 §1, б."В" Регламент (ЕС)2016/679
/Assoc. Prof. Kalin Ivanov, MPharm, PhD /