



Statement

Subject: competition for the academic position of "Professor" in the scientific specialty "Technology of dosage forms", field of Higher Education 7. Health care and sports, professional direction 7.3. Pharmacy for the needs of the "Assistant Pharmacist" specialty in the Medical College, Trakia University - Stara Zagora, announced in the State Newspaper, issue 99/ 13.12.2022

By: Prof. Zlatka Dimitrova Dimitrova, Dsci, ESL "Social Pharmacy and Pharmacoeconomics", Department of Physical Chemistry, Faculty of Chemistry and Pharmacy, SU "St. Cl. Ohridski", elected as a member from the quota of external members of the scientific jury in execution of order No. 303/7.02.2023. of the Rector of Trakia University – St. Zagora, Prof. Dr. D. Yarkov.

1. General presentation of the procedure

1.1. Legal basis of the procedure

The competition for the academic position "Professor" in a professional direction 7.3. Pharmacy, in the scientific specialty "Technology of drug forms", for the needs of the specialty "Assistant Pharmacist" in MK, Trakia University - Stara Zagora, is announced in SN no. 99/ 13.12.2022.

1.2. Participants in the competition

Documents for participation in the competition were submitted within the legal deadline by a single candidate - Associate Professor Krum Stefanov Kafedjiiski, Ph.D., at the Medical College, Trakia University - Stara Zagora. The set of documents provided and the attached electronic copies have been prepared in accordance with the requirements of the regulations relevant to this procedure - the Academic Staff Development Act (ASDA), the Regulations for implementation of the Academic Staff Development Act in the Republic of Bulgaria and the current institutional Regulations on the conditions and the procedure for acquiring scientific degrees and occupying academic positions at Trakia University - Stara Zagora.

1.3. Eligibility of the candidate.

The first meeting of the Scientific Jury, held on 20.02.2023, on the basis of the materials distributed a few days before the meeting to all members of the Scientific Jury, unanimously accepted that the scientific production for participation of Associate Professor Krum Stefanov Kafedjiiski, Ph.D in the competition corresponds to the minimum national requirements and the additional requirements of the Regulations for the conditions and procedures for acquiring scientific degrees and holding academic positions at the Trakia University- Stara Zagora and allowed it to be evaluated on the merits of the competition.

2. General presentation of the candidate

2.1. Biographical data

Krum Stefanov Kafedjiiski was born on November 6, 1977 in the town of Dupnitsa. He graduated from the English language high school "Acad. L. Stoyanov", Blagoevgrad and majored in pharmacy at MU-Sofia in 2002 (No. 012079/ 30.01.2003). He holds a recognized specialty in "Pharmacology and Pharmacotherapy", MU-Varna, Diploma No. 4802/ 07.07.2022 and has 2 qualifications - 2000: Practical training in the field of compound formulation, CETMED, Porto, Portugal and 2008-2011: Specialization at Novo Nordisk, Copenhagen, Denmark in the field of TDF.

He worked for 2 years as a master pharmacist at Sevex Pharma, Bulgaria, 4 years as a Senior Clinical Research Associate at Quintiles and Worldwide Clinical Trials, Bulgaria, 3 years as a Clinical Operations Manager, CTG Bulgaria LLC and 2 years as a Clinical Team Leader , Bulgaria. He is currently the Head of the Clinical Trials Operations Department, "Ergomed Bulgaria" LLC and a Consultant at Kaf-Inova Pharma LLC.

During 2003-2006 developed a dissertation in Austria on the topic: "Development and evaluation of novel excipients for multifunctional drug delivery systems" and was awarded the scientific degree "Doctor of Natural Sciences." He presents Certificate from HAK for recognition of scientific degree "DOCTOR", awarded in Austria in scientific specialty 03.02.01 - Technology of dosage forms and

biopharmaceutics from 11/2007. In September 2015 he had a qualification as an Associate Professor in the Department of "Pharmaceutical Sciences and Social Pharmacy", Sector "Technology of Dosage Forms" in the Faculty of Pharmacy of MU-Pleven, from 10.2022. is an Associate Professor in "Technology of dosage forms" at the Medical College of Trakia University - Stara Zagora. He has good computer literacy and uses 4 languages: English, German, Danish and Russian. He is a member of the Bulgarian Association for Clinical Trials (BACT), the German Pharmaceutical Society (APV) and the American Pharmaceutical Association (AAPS).

3. Evaluation of the candidate

The evaluation of the candidate was carried out in accordance with the requirements of the Academic Staff Development Act in the Republic of Bulgaria, the Regulations for the Implementation of the Academic Staff Development Act in the Republic of Bulgaria and the Regulations on the Terms and Conditions for the Acquisition of Scientific Degrees and Holding Academic Positions at TU in the city of Stara Zagora according to the following criteria:

Criterion №1: Presence of acquired educational and scientific degree "doctor", which for the specialties of the regulated professions must be from the same specialty.

The candidate submits a Certificate from the HAK for the recognition of the SCIENTIFIC DEGREE "DOCTOR", awarded in Austria in the scientific specialty 03.02.01- "Technology of dosage forms and biopharmaceutics" from 11/2007 with subject: "Development and evaluation of novel excipients for multifunctional drug delivery systems", Year of defense: 2006. The scientific specialty of the candidate is identical to the scientific specialty for which the competition was announced.

Criterion №2: Have held the academic position of "Associate Professor" at the same or another higher education institution or research organization for not less than two academic years or not less than five years, or: (a) have been lecturers, including part-time lecturers, or members of a research team at the same or another higher education institution or scientific organization, or (b) have been practitioners and have proven achievements in their field.

The candidate presents diploma No. C 0039/ dated 07/06/2015 for the academic position of "Assoc. Professor" in the scientific specialty 03.02.01 Technology of Pharmaceutical Forms and Biopharmaceutics at the Faculty of Pharmacy, Medical University of Pleven, which position he held until 07. 2022, and from 09. 2022 holds the same academic position in the scientific specialty 03.02.01 Technology of Dosage Forms at the Medical College of Trakia University - Stara Zagora.

Criterion #3: To have submitted a published monographic work or equivalent publications in specialized scientific publications, which do not repeat those submitted for the acquisition of the educational and scientific degree "Doctor", the scientific degree "Doctor of Sciences" and for holding the academic position "Associate professor" .

A monography (habilitation work) on the topic: Oral delivery of therapeutic peptides. New formulation approaches is presented in the candidate's report., year of publication: 2022.

Criterion #4: To have presented other original scientific research works, publications, inventions and other scientific and scientific-applied developments, which are evaluated as a whole.

The candidate, Associate Professor Krum Stefanov Kafedjiiski, PhD, presents his scientific output in 2 lists, prepared by sections, in accordance with the latest amendments to the Academic Staff Development Act and the Regulations for the Implementation of the Academic Staff Development Act in the Republic of Bulgaria:

List of the complete scientific production of the candidate and List of publications of Assoc. Prof. Krum Stefanov Kafedjiiski, PhD for participation in the competition after occupying the academic position of "associate professor"(2015-2022). I accept the second list of publications of Assoc. Prof. Krum Stefanov Kafedjiiski, PhD, when writing this opinion, because it includes the scientific publications of the candidate after holding the academic position of "associate professor". The applicant's report of compliance with the minimum national requirements is also prepared on the basis of this list/2015-2022/.

The candidate has submitted a certificate-declaration that the scientific works, citations and other evidence for the individual scientometric indicators in the submitted certificate for the fulfillment of

the minimum national requirements under Art. 2b of ASDARB for occupying the academic position of "professor" in professional field 7.3 Pharmacy, were not used by him to acquire the educational and scientific degree "doctor" and to occupy the academic position of "associate professor" in the same professional field, as well as for occupying in an academic position in another professional direction. The scientific output of the candidate covers a wide range of the scientific specialty "Technology of dosage forms", and it can be conventionally divided, in my opinion, into the following 4 directions:

The first direction: Creation and application of a new original Thiomers technology for DDS. The creation of the new original Thiomers technology for drug delivery systems (DDS) is the fruit of collective development led by Prof. Dr. A. Bernkop-Schnürch, Austria. Thiolated polymers are new hydrophilic polymers obtained by the covalent bonding of sulfhydryl ligands. As a result of immobilization of thiol groups on already well-established polymers such as polyacrylates or chitosans, the following characteristics are greatly improved: mucoadhesive properties, increased permeation effect, ability to provide controlled drug release, enzyme inhibitory properties, in situ gelling properties and thiomers are able to reversibly inhibit efflux pumps.

In this scientific direction, 1 review article was published in a peer-reviewed journal and a monograph (habilitation work) was presented on the topic: Oral delivery of therapeutic peptides. New formulation approaches, year of publication: 2022.

The second direction: Development of a dosage form of insulin for oral administration, which began as a collective development during specialization at Novo Nordisk, Copenhagen, Denmark. Oral peptide delivery systems are a constant challenge for scientists because of their unfavorable physicochemical properties and small absolute oral bioavailability (of most peptides and proteins < 1%). To overcome these problems, different formulation strategies have been used: SEDDS, SMEDDS and SNEDDS.

In this scientific direction, there are two invention patents and 1 participation in an international scientific project.

The third direction: Scientific and applied technological research with original solutions:

- Development of pharmaceutical compositions containing L-alpha-glyceryl phosphoryl choline with nootropic therapeutic activity in the form of oral hard gelatin capsules and powder for oral solution. The research is protected by two patents.

- Development of a stable pharmaceutical composition of an oral solution containing Metamizole sodium monohydrate. Based on the research, a product registration file was prepared under the trade name Omalgin, oral drops solution, Danson-BG OOD. Date of first authorization 25.10.2019

- Development and in vitro research of a new Alginate Raft - forming oral suspension, which offers effective symptomatic treatment of the clinical manifestations of GERD - acid regurgitation, increased gastric acidity, indigestion after eating. Based on the research, a registration file was prepared for the medicinal product under the trade name Gastroprotect Raft oral suspension, Adipharm EAD, and authorization for the market was obtained - 02.11.2015.

- Development of a composition and process for the production of a gastro-resistant tablet with the release of a low dose of 100 mg acetylsalicylic acid in the intestinal tract. The medicinal product was introduced to the market under the trade name Acessal Protect 100 mg gastro-resistant tablets, Chimax Pharma LLC.

- Development of a pharmaceutical composition of powder for oral solution containing Acetylcysteine. A pharmaceutically acceptable stabilizer of acetylcysteine has been identified. A new method of masking an unpleasant taste has been developed using the excipient Kleptose Linecaps 17 (maltodextrin) - Roquette. The medicinal product is on the market under the trade name AceCys 200 mg powder for oral solution and AceCys acute 600 mg powder for oral solution, Chimax Pharma LLC.

- A stable product with fixed properties was developed in the form of oral tablets containing inosine acedoben dimepranol 500 mg as active substance and with immediate release of the active substance. Inosine acedoben dimepranol (inosine pranobex) is an immunomodulator indicated for the treatment of viral infections. Based on the research, a product registration file was prepared, on

the basis of which a production permit was issued under the trade name Ino-Protect 500 mg tablets, manufacturer Adipharm EAD, holder of the authorization for use TEVA Pharma EAD, Bulgaria, 10.05.2022.

- A pharmaceutical composition of syrup containing a double dose of Inosine Acetoben Dimepranol has been developed. The effect of reducing the sugar syrup content was investigated in accordance with the guidelines of the European Guidelines for the development of medicinal products intended for use in pediatrics in the treatment of pediatric patients suffering from diabetes. The product is registered in Bulgaria under the name Ino-Protect 100 mg/ml syrup, manufacturer Adipharm EAD, holder of the authorization for use TEVA Pharma EAD, Bulgaria, 10.05.2022.

A total of 7 articles have been presented in this scientific direction, of which 6 have been published and 1 is under print in scientific publications, referenced and indexed in world-renowned databases with scientific information. He also has two patents.

In the 4th direction - there are a total of 4 articles, of which 2 are published in scientific publications, referenced and indexed in world-famous databases with scientific information and 2 - in peer-reviewed journals, of which 1 is in print and all are in the field of pharmacotherapy. I have accepted the author's reference for the contributions of the candidate's scientific works.

Criterion No. 5: The applicant meets the minimum national requirements under Art. 2b, para. 2 and 3, respectively, to the requirements under Art. 2b, para. 5 of the Academic Staff Development Act in the Republic of Bulgaria.

The presented scientific production in quantitative and qualitative terms significantly exceeds the minimum national requirements for occupying the academic position of "professor" in the field of higher education 7.0 "Health and sports", professional direction 7.3 "Pharmacy". With no less than 550 points required, the scientific production presented by Assoc. Prof. Krum Stefanov Kafedjiiski, PhD, calculated according to the criteria, is 8463 points. All citations of his publications are included in the reference provided to him. I will allow myself to recognize 292 citations for the period 2015-2022 or 4380 points, where the total number of points according to the criteria is 5118, nearly 10 times more than the minimum requirements.

Criterion No. 6: That there is no proven plagiarism in scientific works according to the law.

I do not find any information about proven plagiarism in the scientific works of the candidate Assoc. Prof. Krum Stefanov Kafedjiiski.

Additional criteria

Assoc. Prof. Krum Stefanov Kafedjiiski, PhD, is the only candidate in the competition, which circumstance excludes the need to analyze the additional criteria in accordance with Article 27, Paragraph 4 of the ASDA. However, I will touch on them as well.

Criteria related to the educational activity: Assoc. Prof. Krum Stefanov Kafedjiiski, PhD conducts lectures and practical exercises on TDF and Biopharmaceutics, participates in semester and state exams. He is the author and co-author of the study programs on Technology of dosage forms.

Criteria related to scientific research activity:

Data on the candidate's participation in 4 national scientific and educational projects and 1 international scientific project are presented, and he is a reviewer of 1 scientific project at MU-Varna in 2020.

Recommendation: In the future already as a professor to work more with students and PhD students on scientific projects and to participate with them in publications and reports on scientific forums as well as being the author or co-author in a new TDF textbook.

CONCLUSION

The documentation submitted for the competition by Assoc. Prof. Krum Stefanov Kafedjiiski, PhD fully meets the requirements of ASDA in RB, PP ZRAS in RB and the Regulations for the terms and conditions for acquiring scientific degrees and occupying academic positions at Trakia University - Stara Zagora far exceeding the minimum requirements for holding the academic position of "Professor". The candidate is an accomplished teacher and respected scientist with indisputable scientific achievements and authority in academic circles, knows how to work in a team and is a

respected and sought-after expert-consultant with significant own theoretical and applied contributions and developments implemented in practice in the field of the Technology of dosage forms. On this basis, I give a highly positive assessment to the candidate, I will vote "Yes" and I strongly recommend to the members of the Scientific Jury, whom I deeply respect, to elect Assoc. Prof. Krum Stefanov Kafedjiiski, PhD as "Professor" in the Technology of Dosage Forms, field of higher education 7. Healthcare and sport, professional direction 7.3. Pharmacy for the needs of the "Assistant Pharmacist" specialty at the Medical College, TrU- Stara Zagora.

18.03.2023
Sofia

Prepared the opinion:
/ Prof. Zl. Dimitrova, DSci