

REVIEW

BY ASSOC. PROF. ALBENA ZLATAREVA MD, PHD

Department of "Economics and Health Management"

Faculty of Public Health, Medical University - Varna

member of the scientific jury for academic position "Associate Professor" (published in SG, issue 105/11.12.2020), approved by order of the Rector РД-29/05.02.2021 in the field of higher education 7. Healthcare and sports, professional field 7.1 Medicine, scientific specialty "Pharmacology" for the needs of teaching in the specialty "Assistant Pharmacist", Department of Pharmacy

Only one candidate participates in the competition - Lyubina Racheva Todorova, MD, PhD

I. Analysis of the candidate's career profile.

Dr Lyubina Todorova, MD, was born in 1967 in the town of Yambol. She graduated at High School in his hometown in 1985, and his higher education in human medicine at the Higher Medical Institute (now the Thracian University, Medical Faculty) - Stara Zagora (1991).

During the period 1991 to 1999 she worked as a physician at the ward of internal diseases at the Regional Hospital in the city of Yambol.

In 1997 she acquired a degree in internal medicine at the Medical University - Sofia, and in 2000 – a degree in clinical haematology at the Medical University - Varna

Dr L. Todorova has specialized in Germany (in June and July, 2002) at Paul-Ehrlich Institute: Training for dossiers assessment of blood- and plasma-derived medicinal products and the USA (November- December, 2003) - US Department of State, International Visitors Program - Infectious Diseases and the HIV Pandemic.

During the period 2013-2018 was a part-time PhD student at Medical Faculty of Medical University - Sofia and in April 2018 successfully defended a PhD on "Pharmacological modulation of pain: experimental, clinical and regulatory studies" to acquire scientific doctor's degree.

Since 2000 he has been working at the BDA. Initially as a chief Expert/Head of Unit "Blood-derived medicinal products" Directorate "Biological products" and subsequently as a Head of the Department "Control of transfusion system" (2007-2010) and subsequently Head of Department "Marketing Authorisations of Medicinal Products" (2010 and present)

Dr L. Todorova has very good analytical, computer and communicational skills incl. team working.

She has mastered a number of pharmacological, clinical-laboratory, bio statistical and other methods, as well as work with specialized research equipment with software.

She is fluent in spoken and written English and French, which allows her to handle quickly and easily scientific literature.

Currently, Dr Lyubina Racheva Todorova, MD is a member of the Standing Committee on Medicinal Products at the European Commission (Standing Committee). She has been working as a member of the Committee for Orphan Medicinal Products at EMA since 2017.

Dr Lyubina Racheva Todorova, MD, is a member of the Transparency Commission at the Council of Ministers during the period 2008-2012, and since 2016, to date. Additionally, in 2007-2013 she was a member of CAT (Committee for Advanced Therapies) at the European Medicines Agency.

II. General description of the submitted materials in the competition.

The applicant has applied the full set of documents, according to Rules on the Conditions and Procedures for Acquiring science degrees and holding academic positions in the University named "Prof. Zlatarov " - Burgas, as follows: An application to the Rector of the University "Prof. Asen Zlatarov " - Burgas, for admission to the competition with an inventory of documents; Summaries of reviewed publications in Bulgarian as well as CV in EuroPASS format; diploma for higher education (Human Medicine and for acquired speciality in internal medicine from – Medical University Sofia, and for acquired speciality of Clinical Haematology issued by the Medical University of Varna, diploma for the educational and science degree “Doctor” from 2018 issued by MU - Sofia), list of publications, conferences and a successfully finished project in 2016 where she took part during her training in Doctor degree.

Documents are submitted as paper copies and on electronic medium.

III. Evaluation of the candidate's scientific works for the overall academic development.

The scientific publications submitted by Dr Lyubina Todorova have proven science-theoretical, applied and scientific- confirmatory character.

The applicant takes part in the competition with a total of 23 scientific papers as follows:

- Monograph, which is presented as a major habilitation thesis;
- 6 publications in indexed scientific journals, in world-famous databases with scientific information (Scopus and Web of Science) ;
- 17 publications in unreferred journals and scientific peer review or published in the collective volumes;

The monographic work of Dr Lyubina Todorova, MD, is under print, and the author has provided the reviewers with a comprehensive summary of his work.

The scientific articles submitted for the participation in the competition are printed in different journals and collections in the field of pharmacology, rare diseases, etc., with the exception of an article that is under print.

Publication activity of Dr Lyubina Todorova, PhD, is defined with good international visibility.

In 7 of the presented articles Dr Todorova is the first author, and in the remaining 16 – second or subsequent author. In her self-esteem, the candidate separated the entitlements points for each presented scientific work, in proportion to the number of authors. The applicant’s score in different groups of indicators is as follows: **Indicator A: 50 pts. Indicator B: 100 pts. Indicator C -215 pts., Indicator D-72 pts.**

The fields of Dr Lyubina Todorova’s research, and respectively the contributions to them, can be summarized in three main areas:

1. **Regulatory** – the prepared by the applicant monograph and 5 of her publications, presented for competition, are in this area. One of them - Committee for Advanced Therapies (Todorova L as a member of CAT) Use of unregulated stem-cell based medicinal products, CAT; The Lancet, vol. 376, August 14, 2010, was published in the prestigious scientific journal with a high IF for 2010 g. - 35.434.

2. **Pharmacology of the nervous system (pain syndromes, cerebrovascular disease)** - 5 of the articles presented by the candidate are in this field

3. **Pharmacology in elderly.** Three of the publications submitted by the candidate have this focus.

The research work of Dr. Lyubina Todorova, MD, clearly demonstrates relevance and effectiveness. The main scientific contributions of the overall work of the applicant include: the role and location of antiepileptics in the treatment of diabetic polyneuropathy; establishing guidelines for pharmaco-therapeutic approaches in patients over 65 years of age for various

clinical conditions; Initiation of procedures for complete harmonization of the dossier/product information (Summary of Product characteristic and a package leaflet) regarding their use in elderly (posology, need for dose changes, dose range depending on the kinetics of active substances in the patient population over 65 years).

Candidate is working actively as a member of the Committee for Orphan Medicinal products (COMP) at the European Medicines Agency, and prepares reports on applications and documentation for the orphan designation on monthly basis. (*Note: The entire documentation of this committee is a confidential; therefore, the same cannot be pointed out publicly*). The decisions of the Committee are published on the EMA's website. (*Note: Decisions do not specify the names of rapporteurs*). The evaluation focuses on the results of non-clinical in vitro and in vivo studies in (valid) animal models and preliminary data from clinical trials in patients.

IV. Evaluation of the monographic work or equivalent publications submitted for participation in the competition

The candidate has presented a monograph, examining the current picture, problems and challenges of pharmaceutical regulation, on the topic: *Current aspects of pharmaceutical regulation*.

The monograph includes 8 parts where the important aspects of pharmaceutical regulation have been discussed: such as existing processes and procedures for issuing marketing authorizations of medicinal products, new developments in the light of the rapidly changing situation in the country and Europe (the world) due to pandemic from COVID-19, as well as specific issues that are often faced by those employed in the field of drug regulation. The monograph also systematizes and presents the main types of medicinal products and the procedures by which they are authorized, as well as the requirements for documentation for quality, safety and efficacy, paying special attention to the so-called *generic products* and the extent to which they are safe and effective compared to the 'originals'. In addition, the current trends in drug regulation, the development of innovative high-tech drugs, as well as those for the treatment of rare diseases are presented. The author comments existing problems, both from a legal and an ethical point of view.

I am convinced that the applicant's monograph is of great practical character and applied scientific importance.

VIII. General assessment of the candidate's compliance with the mandatory conditions and the mandatory quantitative criteria and scientometric indicators according to Rules on the Conditions and Procedures for Acquiring science degrees and holding academic positions in the University "Prof. Asen Zlatarov"- Burgas

Area of higher education 7. Healthcare and sports, professional field 7.1 Medicine, scientific specialty "Pharmacology" for the needs of teaching in the specialty "Assistant Pharmacist", Department of Pharmacy

Table 1. Minimum required credits by indicator groups for the different scientific degrees and academic positions

| | | | |
|-------------------------|--|---|----------------------|
| Group indicators | Associate Professor according to DASRBA and PURPNSZAD | Associate Professor according to PURPNSZAD for | Dr. Lyubina Todorova |
|-------------------------|--|---|----------------------|

| | | University "Prof. Dr. Asen Zlatarov » | |
|-------|-----|---|-----|
| A | 50 | 50 | 50 |
| B | - | - | - |
| IN | 100 | 100 | 100 |
| G | 200 | 220 | 215 |
| D | 50 | 60 | 72 |
| E | | 20 | 80 |
| TOTAL | 400 | 450 | 527 |

IX. Conclusion

The candidate **meets** the required and specific conditions and scient metric criteria pointed out in DASRBA and Rules of University "Prof. Asen Zlatarov"- Burgas, for holding the academic position of "Associate Professor".

X. Proposal for holding the position

The materials submitted by the candidate for the open competition show that Dr. Lyubina Todorova, MD, fully meets the requirements for holding the academic positions "Associate Professor" under the Development of Academic Staff in the Republic of Bulgaria Act (**DASRBA**), the Rules for the Application of the Development of Academic Staff in the Republic of Bulgaria Act and Regulations of the Burgas University "Prof. Asen Zlatarov". Presented scientific works and evidences of scientific activities meet the quantitative and qualitative criteria and have a high scientific level. The same is witness for long-term devotion to science and the problems of areas in which the candidate has Publication activity.

All presented documents certifying that the candidate is a proven specialist in practice and possess numerous scientific and practical achievements. Based on my personal impressions, I can confidently say that the candidate has the necessary qualifications for pedagogical and methodological competence.

This gives me a reason to give my positive assessment and to recommend the Academic Jury to render a positive decision on Dr Lyubina Todorova, MD, filling the academic position of "Associate Professor" in field of higher education 7. Healthcare and sports, professional field 7.1 Medicine, scientific specialty "Pharmacology" for the needs of teaching in the specialty "Assistant Pharmacist", Department of Pharmacy.

29.03.2021

Albena Zlatareva