



## OPINION

**Of Prof. Dr Mila Vasileva Vlaskovska, MD, PhD, DSc, Corresponding Member of BAS,  
Medical Faculty, Medical University, Sofia**

**Subject: Open competition for academic position "Associate Professor" in higher education 7. "Health and Sports", a professional direction 7.1 "Medicine" scientific specialty "Pharmacology" for the needs of the College of Medicine at Bourgas University "Prof. Asen Zlatarov" announced in the State Gazette, issue 105/11.12.2020 for the needs of teaching in the specialty "Assistant Pharmacist", Department of Pharmacy**

One candidate has submitted application and documents for participation in the competition only: Dr Lyubina Racheva Todorova, Director of the Directorate in the Bulgarian Drug Agency (BDA). Her application is approved and admitted for participation by the relevant committees at the University.

I declare that I have joint publications with the candidate.

### ***Career development of Dr Lyubina Todorova.***

Dr Todorova graduated in human medicine in 1991. In 1997 she acquired a degree in internal medicine, and in 2000 - a degree in clinical haematology. Since 2001 Dr Todorova has been working at the BDA. Currently, she is the Director of the Directorate for Marketing Authorisation of Medicinal Products. She quickly enters the problems of regulation of blood-derived and synthetic medicinal products, which is facilitated by the specializations - 2002 in Germany, 2003 - USA, 2008 - the Netherlands.

In 2018 she defended a dissertation for the degree of Doctor. As a scientific consultant of the doctoral student, I can confidently say that she approached the problem extremely thoroughly, responsibly and creatively and started a series of dissertations dealing with fundamental, clinical and regulatory aspects of different drug groups in our country.

Furthermore, Dr Lyubina Todorova is a prominent specialist involved in the responsible committees of EMA related to drug regulation, such as: Member of the Standing Committee for Medicinal Products at the European Commission (Standing Committee) Member of the Committee for Orphan Medicinal Products (COMP) at EMA, was an alternate member of CHMP as well as member of the Transparency Commission to the Council of Ministers (current), member of the Committee for advanced therapies (Committee for advanced therapies) (2008 – 2013).

In the last 8 years Dr Todorova is a vice-chair of the Commission for medicinal products to the BDA, of which I am chair and I have a great impression of its performance, thoroughness and responsibility in performing tasks.

In summary, I can confidently say that Dr Lyubina Todorova is built with international and national weight and fame expert in the field of pharmacology and drug regulation. The possession of two clinical specialties - internal medicine and haematology make the application especially suitable for the offered position, as the pharmacology in the Medical College must be well connected with the clinical picture.

### ***Research activity***

The candidate participates in the competition with a total of 23 scientific papers as follows:

- Monograph, which is presented as a major habilitation thesis; ISBN 978-954-615-190-2
- 6 articles in indexed scientific journals, in world-famous databases with scientific information (Scopus and Web of Science);
- 17 publications in non-peer reviewed /unreferred journals and scientific peer review or published in the collective volumes

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

The total number of citations is 20 in Bulgarian, according to the attached reference from the Central Medical Library - Medical University, Sofia. **137 citations were found in the SCOPUS database.**

The publishing activity of Dr Lyubina Todorova, MD, is characterized by good international recognition.

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 credits 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 credits; Indicator B: 100 credits; Indicator C - 215 credits; Indicator D-72 credits.**

Dr Lyubina Todorova's areas of research interest, and its scientific contribution can be summarized in three main areas:

1. **Contemporary problems of drug regulation.** In this field, Dr Todorova publishes a monograph on *Current issues of pharmaceutical regulation* and is the author/co-author of 5 publications.

The monograph includes 8 parts, where discussed important aspects of pharmaceutical regulation, the existing processes and procedures for marketing authorization of medicinal products, new moments in the light of current dynamic volatile, changing situation in the country and Europe (the world) in view of the pandemic of COVID-19, as well as specific issues that are often faced by those involved in the field of drug regulation.

One of the publications - 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 world-famous scientific journal with a high **IF for 2010 -**

35.434. Dr Todorova is a recognized in our country and within the committees of the EMA competent and respected specialist in the field of drug regulation. In this context, I would like to note that Dr Todorova is a member of the Editorial Board of the journal Science of Pharmacology. Members of the editorial board are Prof. Harald Enzmann, Chairman of the CHMP at the EMA and Prof. Andreja Laslop - a member of the CHMP at the EMA and Director of the Medicinal Products Authorization Directorate at the Austrian Medicines Agency.

Dr Todorova works actively as a member of the Committee for Medicinal Products for Rare Diseases (COMP) of the European Medicines Agency, as monthly prepare reports on applications and documentation for orphan designation of different molecules.

**2. Pharmacology of neurotrophic medicinal products used to treat different in mechanism painful symptoms.**

As already noted, Dr Todorova's dissertation examines important experimental models and clinical trials of analgesics and antidepressants. 5 of the articles, submitted by the applicant are in this field, and one of them was published in the journal with impact factor.

**3. Features of pharmacotherapy in elderly:**

3 of the articles, submitted by the applicant are in this field.

Given the importance of the problem of regulating clinical trials of drugs in the elderly due to the aging population and the experience gained by Dr Todorova, I would recommend preparing a monograph in this area. There is a scientific sub-committee established at EMA, which is working very actively in this direction and on the other hand, the interest of healthcare specialists (incl. physicians, pharmacists and regulators) is increasing progressively.

***Teaching activity***

Dr Lyubina Todorova participates in extracurricular activities: qualification courses for doctors and master pharmacists and in courses for classified persons in health care and the pharmaceutical industry.

Summarizing her teaching activities, I can definitely define her as a constantly evolving expert in pharmaceutical regulation, scientist and lecturer who fully meets the requirements of DASRBA and the Regulations on the terms and conditions for acquiring and holding academic positions at the University "Prof. Dr Asen Zlatarov" Burgas and its annexes for holding the academic position of associate professor.

**Notwithstanding the above arguments in support of the high level of Dr Todorova as a prominent specialist in the field of competition, below are presented the numerical expressions of the mandatory conditions and quantitative criteria and scientometric indicators according to the 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 RIDASRBA	Associate Professor according to RCPASDHAP for University "Prof. Dr. Asen Zlatarov"	Dr Lyubina Todorova
A	50	50	50
B	-	-	-
IN	100	100	100
G	200	220	225
D	50	60	72
E		20	80
TOTAL	400	450	527

## CONCLUSION

I know the candidate for AP "Associate Professor" **Dr Lyubina Racheva Todorova, MD** in person and I am convinced that with her impressive experience, expertise and competencies, incl. in the scientific field of the open competition she will contribute to raising the prestige of the University. Dr Lyubina Todorova is a hard-working person with an extremely broad general and professional knowledge, excellent in new technologies and liked as a lecturer.

Based on all the above, I strongly recommend to the esteemed Scientific Jury and the esteemed Faculty Council to award the academic position of "Associate Professor" to **Dr Lyubina Racheva Todorova, MD** in professional field 7.1. Medicine, scientific specialty "Pharmacology" for the needs of teaching in the specialty "Assistant Pharmacist", Department of Pharmacy at the University "Prof. Dr Asen Zlatarov" Burgas.

Sofia, PREPARED THE OPINION

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