

## REVIEW

by

**Prof. Dr Krasimir Gigov, MD**, Department of Disaster Medicine and Marine Medicine, Faculty of Public Health, Medical University – Varna, member of a scientific panel for awarding the academic position “Professor” (published in The Gazette, No 17/26.05.2021), approved by order of the Rector RD-No P-109-203/26.04.2021, higher education field 7. Healthcare and Sport, professional field 7.1. Medicine, subject Pharmacology and Pharmacotherapy (Drug Policy) – one, 0.25 full-time position for the needs of the Department of Pharmacology, Toxicology and Pharmacotherapy, Faculty of Pharmacy; additional requirements of the competition: not to apply the provision of Art. 137, para 1, item 6 of the Rules for Academic Staff Development of the Medical University in Varna, and the sum of the points for the indicators from item 13 to item 22 for field 7. Healthcare and Sport shall be one hundred, without applying the requirement that indicator 14 shall account for more than 80 points.

One candidate participated in the competition – **Associate Prof. Dr. Albena Zlatareva, MD**.

### **I. Analysis of the candidate's career profile.**

Albena Zlatareva completed her higher education in medicine at the N. P. Pavlov Military Medical Academy in Plovdiv in 1992. In 1998, she completed a degree in Anaesthesiology and Resuscitation and in 2014 she successfully defended a PhD in Pharmacology (including Pharmacy and Chemotherapy) at the Medical University of Sofia with the thesis *Financing the Pharmacotherapy of Rare Diseases*.

In May 2016, the candidate was awarded the educational and scientific degree Associate Professor in the subject of Clinical Pharmacology and Therapy at the Medical University of Varna.

Associate Prof. Albena Zlatareva, MD has extensive professional experience in the field of national drug policy and drug regulation in Bulgaria, and has successively been: a MP assistant at the Health Committee of Parliament in the period 2005-2009 in connection with the establishment and implementation of the legal framework in the drug sector in Bulgaria; Deputy Director of Drug Policy and Control at the National Health Insurance Fund in the period 2009-2010; member of the Committee on the Positive Drug List during the same period; member of the Accreditation Board at the Ministry of Healthcare 2009-2010; methodological manager and member of working groups on changing the regulatory framework in the drug sector in the period 2009-2010; adviser to the HIV/AIDS Prevention and Control Programme in 2012 in the field of drug policy and the application of good practices to improve the access to diagnosis and treatment in the affected communities.

The candidate has over 17 years' experience in pharmaceutical companies in the field of drug policy, drug regulation and market access.

Associate Professor Dr. Albena Zlatareva also has over 10 years of academic experience in various medical universities in the field of anaesthesiology and resuscitation, pharmacotherapy, drug policy and pharmacoeconomics. From 1.04.1993 to 30.11.1995 she was assistant professor at the Anaesthesiology, Resuscitation and Intensive Therapy Clinic, MU - Plovdiv. During the period 2014-2016, she was a part-time lecturer in Drug Policy, FPH, MU Varna and the Master's Programme in Public Health and Health Management, teaching in Russian in the elective discipline Comparative Analysis of Health Systems and others. From 2016 to date, the candidate has worked as an associate professor at the

Medical University of Varna and has been the dissertation director of 2 graduates and a referee of 2 graduates; and dissertation director of 3 PhD students who successfully defended their theses;

She has worked as a reviewer in several international scientific magazines: the Balkan Medical Journal – 2015; the International Journal of Educational Policy, Research and Review, 2021 and the Value in Health, 2021.

Associate Professor Zlatareva was also a member of the scientific panel for the academic position of Associate Professor (published in The Gazette, No 105/11.12.2020), approved with order of the Rector RD-29/05.02.2021 of MMA in Varna in higher education field 7. Healthcare and Sport, professional field 7.1. Medicine, scientific discipline Pharmacology for the purposes of training of Dr. Lyubina Racheva Todorova, MD in the Assistant Pharmacist degree programme in the Department of Pharmacy.

The candidate has been a member of organisations of great social importance, such as ARPharM, the Confederation of Employers and Industrialists in Bulgaria, AmCham, where she actively sat on the health committees, prepared documents and proposals for implementation of the European drug policy in Bulgaria /draft National Cancer Plan in Bulgaria/.

She has been the head of campaigns related to the implementation and improvement of the local drug policy, such as a campaign to increase the confidence in vaccines, specifically concerning cervical cancer-related diseases, etc.

Associate Professor Zlatareva has been the head of a number of international projects, such as the Western Balkans Project: a Health Coalition, concerning the setting of healthcare as a priority for the political leadership of the countries from the region by sharing good practices between the countries from the Western Balkans that are candidate EU member-states and Bulgaria for the purpose of health reforms with progress (Assignment For Regional Lead); as well as PEPP (Patient Engagement and Patient power) and *School for Patients* - a projects aimed at improving local health ecosystems and enhancing the role of patient organisations as an equal partner of the institutions with a focus on Bulgaria and the countries of the Western Balkans; Economist Intelligent Unit - Breathing in new Era: a comparative analysis of lung cancer policies across Europe. Bulgaria country Lung cancer profile; Project Leader for Bulgaria in the project MSD for Mothers, covering Bulgaria, Romania and Serbia and related to the maternal health care in vulnerable groups, including the Roma population, as well as creative founder and project manager of MSD for Mothers, including 5 countries from the Western Balkans region in partnership with IPPF, aimed at preventing maternal mortality in vulnerable groups from Western Balkan countries such as teenagers and Roma populations during crisis situations, including COVID-19.

The candidate is also a member of the following international projects: Organon – communication and changes: a project aimed at training and informing the different participants in the pharmaceutical system about how a new pharmaceutical company is created; HIP project: a project aimed at analysing local data on the cost of oncological treatment and drafting a policy proposal in the given field; EU enlargement project: a project aimed at assisting candidate EU member-states in the synchronisation of drug policy; Listen, Learn, Lead: a project aimed at better teamwork and policy-making for a better local environment in the field of oncology and vaccines; Lung Cancer Treatment Rate – an international

project aimed at improving the treatment of patients with oncological diseases and focused on lung cancer.

The candidate has also been a project manager of a national scale such as *Population Awareness of the National Vaccination Policy compared to the European One*, Sharing good practices, Development of a new cervical cancer strategy; Project for implementation of a national cancer plan, etc., as well as a member of the projects *Take a Breath*, focused lung cancer, 2019, 2020; Covid-19 Alliance, organised by NGOs, etc.

## **II. General description of the materials submitted under the competition.**

The candidate has enclosed a complete set of documents, in compliance with the Regulations of the Medical University of Varna, as follows: an application to the Rector of the Medical University of Varna for admission to the competition with a list of documents; a European format CV; diplomas for completed higher education (diplomas for completed education in medicine, for acquired specialisation in anaesthesiology from the Medical University in Plovdiv, a diploma for awarded scientific and educational degree Doctor in 2014 from the Medical University in Sofia, a diploma for awarded educational and scientific degree Associate Professor from the Medical University in Varna), a certificate of internship in the respective specialisation and a statement of the academic positions held so far, records of participation in projects and certificates of leadership skills, the art of negotiation; business practices; anti-corruption practices, etc. The documents are submitted in paper and electronic form.

## **III. Evaluation of the candidate's scientific papers for the overall academic development**

Assoc. Prof. Dr. Albena Zlatareva, MD has an impressive publication rate.

She is the author of 2 monographs, 1 book (bilingual), a textbook (electronic edition), over 54 articles, as well as summaries, and posters for scientific events in the field of drug policy, health and pharmaceutical management.

The scientific papers submitted by Associate Prof. Dr. Albena Zlatareva, MD are of a scientific and theoretical, scientific and applied, and scientific and confirmatory nature. The candidate participates in the competition with a total of 58 scientific works, as follows:

- Monograph on the topic of *Fundamentals and Trends of Drug Policy in the European Union*, which is presented as the main postdoctoral work – 216 pages;
- 15 publications in indexed journals, in world-famous databases of scientific information (Scopus and Web of Science) according to the Academic excerpt for minimum requirements, 6 publications in indexed journals, in world-famous databases of scientific information (Scopus and Web of Science) after the award of the ESD Associate Professor, and 9 publications in indexed journals, in world-famous databases of scientific information (Scopus and Web of Science) until application for the ESD Associate Professor;
- 35 publications in unreferenced journals with scientific review or published in edited collective volumes, 22 cited in the application for occupying the ESD Professor and 13 cited for the ONS Associate Professor;

The articles with which the candidate participates in the competition are published and included in various journals and collections in the field of pharmacology, rare diseases, etc.

In 41 of the submitted articles, Associate Prof. Dr. Albena Zlatareva, MD, is the first or only author, and in the other 13 she is the second or subsequent author. In her self-evaluation, the candidate has divided the points due for every cited scientific paper proportionately to the number of co-authors, and the candidate's points by groups of indicators that I recognise, are as follows: indicator A – 50 points, indicator C – 100 points, indicator D – 550 points.

#### **Iv. Evaluation of the monograph or equivalent publications submitted for participation in the competition**

The candidate has submitted a monograph addressing the problems of drug policy entitled *Fundamentals and Trends of Drug Policy in the European Union*. The monograph examines the different aspects of drug policy in the European Union in their comprehensiveness and depth, focusing on its specific characteristics for the Bulgarian healthcare system. The monograph aims at assisting the process of development of a working European drug policy in Bulgaria as well. The main message is that health costs should be addressed through the prism of investment, and the development of healthcare funding policies would have a direct impact on the local economy, leading to an improvement in the economic indicators related to improving the vital indicators of the nation.

The candidate's monograph is of important scientific and practical and scientific and applied importance.

The areas of research interest of Associate Prof. Dr. Albena Zlatareva, MD and, accordingly, the contributions to them can be summarised in several main directions:

- **Digital training in the field of drug policy**

The candidate has three publications on the subject - all three in international journals, two of which are referenced in international databases. The publications are certain scientific and practical contributions. They stress the need to create and to develop digital forms of continuing education for medical professionals in the field of drug policy, as the data from a survey show that healthcare professionals in Bulgaria and in countries in the Balkan region have the motivation and the desire to build on their training in this field and providing such an opportunity is desired by them. The needs identified by the study and the necessity to set up new, specialised programmes for training medical professionals in the field of management and implementation of national and international strategies and policies in the field of drug policy for enforcement of legislation, implementation of strategies, programmes and policies on a national and international level, the inclusion of such courses will be useful in planning the activities of higher education institutions in Bulgaria and will help to develop their portfolio and attract more learners. The postgraduate courses and programmes offered by the higher education institutions enjoy a high level of trust among the respondents, which once again confirms the role of higher education institutions in the quality of acquiring adequate and modern knowledge. The scientific and applied contributions of the publications in question include the thesis that the use of digital technologies, including medical and medicinal ones, call for an accelerated digitalisation of the healthcare sector, especially in a time of crises, such as the occurring pandemic, and sharply increase the need for rapid changes in the

drug policy of the healthcare and for continuing education of the professionals. The only possible form ensuring fast communication and timely access is the digital one, but it is connected with the demand for new platforms, trained specialists and a regulatory framework (requirements for training and application).

- **Drug policy and drug regulation**

This direction is maintained in all publications. It examines the national drug policy, the tasks before regulators and the pharmaceutical industry, the regulatory framework in the field of the drug sector, the benefits for the society as a whole. Comparisons have been made and the uniqueness of the processes for each country is indicated. The practical contribution of these publications is a clarification of the ongoing drug policy in Bulgaria and internationally and the comparison of the good practices around the world.

Regional drug policy focus: 2 articles (in Bulgarian journals) and project manager of the Western Balkans project are a contribution towards: improving awareness in order to ensure the inclusion of health as a priority for the Balkan countries, using the EU Initiative for the Western Balkans as a catalyst. Facilitating the sharing of the best practices – in order to ensure improved access to healthcare and innovative treatment. Expanding the scope of cooperation and transfer of knowledge from politicians and local institutions to healthcare experts in the region for the purpose of improving the overall health and social welfare of the citizens of the Western Balkans. She authored a proposal for a new non-clinical degree in drug policy and market access to drugs and conducted a course in the topic for the purpose of raising the awareness and producing qualified staff, both in the private and public sectors, and was the editor and author of a textbook in Market Access to Drugs, published by the MU Varna.

Vaccine policy focus – 3 articles and participation in projects on vaccines – contributes to supporting the process of implementing the European recommendations at local level, which will lead to improved access to healthcare services, re-location of the health budget with realised direct and indirect healthcare benefits.

Oncological drug policy focus: participation in projects and scientific publications related to the fight against oncological diseases to help improve the local oncological environment in order to implement good European practices, attract a wide range of stakeholders who make the decisions leading to improved access to screening, diagnosis and treatment of cancer patients.

The book *Drug Policy and Innovation. Roadmap// Bulgarian Pharmaceutical Passport. Roadmap*. (bilingual version) considers the drug policy in the EU and in Bulgaria. It is a contribution to supporting the process of developing a working European drug policy in Bulgaria too.

Focus on patients, as a partner in the devising of a working drug policy: in 4 of her publications, Associate Prof. A. Zlatareva asked questions concerning the process of positioning patients as an equal participant in the process of making the drug policy on a local level, as is the drug policy and its participants by definition. The candidate also participated in projects on this topic.

Focus on the rights in healthcare: 2 specific publications advocate the right to health, including of the vulnerable groups, as well as at a time of crisis situations. The topic of the right to health, as an unwaivable one, directly correlates with the topics of drug policy, patients' rights, including as an equal participant in the devising of the healthcare and drug policy in each EU Member State. This topic can be

traced in all publications by the author, including the projects of which the candidate was in charge and which were dedicated to patients.

- **Good and innovative medical practices**

8 publications are dedicated to this topic. 6 of them in journals with a scientific review and 2 in a Bulgarian journal referenced and indexed in Scopus. They examine problems related to rosacea and its pharmacological treatment, as well as problems in the field of aesthetic surgery and analgesia in similar therapies. The patients' desire for less invasive procedures with a shorter recovery period becomes a constant impetus for innovation in aesthetic surgery. The penetration of sealants, whose application leads to promising and better results in face-lifting, is also a topic of interest. The discussion about whether to use sealants or drainage in face-lifting continues and only in-depth scientific studies will prove the correctness of one or the other opinion. The publications consider the advantage of the employed technique including the use of sealant and surgical suture. Although this method is connected with greater financial costs, the benefits for the patient include a shorter recovery period and faster return to a complete social and emotional life.

- **Regulatory framework in the drug sector**

5 scientific publications in journals and in 7 in Bulgarian scientific journals make an analysis of the regulatory framework, including historically, both in our country and in most European ones, as well as of the impact of these regulations on the drug sector, on individual patients and the society as a whole. These publications, in addition to their theoretical contribution, have a practical one too, showing the experience of different countries, as well as the advantages and drawbacks of the implementation of certain regulations.

- **Pharmacoeconomic and financial aspects of drug therapy**

10 publications in Bulgarian and international scientific publications analyse the cost of pharmacotherapy for a number of diseases, the most resource-intensive of them, and examine the costs incurred by public health funds in Bulgaria and other European countries. Conclusions have been drawn, both with a theoretical and practical contribution to the rational management of the cost of drug therapy.

- **Drug use**

The drug use on a macro- and micro-levels for the entire drug market and for specific therapeutic classes and diagnoses has been investigated. The main direction is in the field of rare diseases and their pharmacotherapy, covered both in the dissertation work as well as in 4 publications in Bulgarian journals and in 4 in international ones.

In 5 publications in Bulgarian and international journals, the pharmacotherapy as well as vaccine prophylaxis of oncological diseases has been studied. They specify which diagnoses are the most resource-intensive, as well as the impact of the new therapies' penetration into oncology therapy on morbidity and the cost of public funds.

6 publications in Bulgarian and international journals address therapies by specific diagnoses (CVD, schizophrenia, rheumatoid arthritis, Crohn's disease, ulcerative colitis, beta-thalassemia, psoriasis) with a great impact not only on the individual patient, but also on society as a whole, which determines the applied contribution of these developments.

- **Clinical trials of drugs**

2 publications, one of which in an impact-factor journal, examined both the motives and the benefits and risks of carrying out clinical trials at the level of all participants in this process. These developments make a theoretical contribution to the fact that so far the participation of patients in clinical trials and their motives and practical contribution to the ethical regulation of clinical studies have not been analysed in our country.

#### **V. Referencing (citation) of the candidate's publications in national and foreign literature (publication image).**

The candidate covers the regulatory requirements for citation of the scientific papers (110 points according to the Academic record) and has also presented an additional a list of cited publications (120 points according to the Academic record), which undoubtedly shows the high international visibility of the candidate's scientific output.

#### **Vi. Complex, qualitative evaluation of the educational and methodological and teaching work, including advising students, PhD students, and residents as a dissertation director.**

The candidate has the necessary teaching experience, starting as an assistant professor at the Medical University of Plovdiv from 1993 to 1996 in the discipline Anaesthesiology and Resuscitation. In the academic years 2014/2015 and 2017/2018, she was a full-time lecturer in the Master's programme in Public Health and Health Management, teaching in Russian in the elective subject Comparative Analysis of Health Systems at the MU in Varna.

Since 2016, the candidate has held the position of Associate Professor at the Medical University of Varna, delivering lecture courses in Drug Policy, conducting seminar and practical classes for students, PhD students, and residents in the field of drug policy such as *Pharmaceutical business and market access to drugs* (Department of Postgraduate Education); *Market access to drugs – current trends*, and a number of others.

Since her appointment, she has been engaged in scientific and teaching and research work with her students and graduates and PhD students of whom she has been in charge. Associate Prof. Dr. Albena Zlatareva has submitted academic records and certificates of the trainings conducted by her, which confirm her long teaching experience.

The successful defences of three PhD students (Dr. Milko Kovachev, Dr. Spartak Milev, and Dr. Branimir Brankov), whose dissertation director was Associate Prof. Zlatareva, are clear evidence of her good methodological work with PhD students.

The management of and participation in a number of national and international projects prove that the candidate continuously maintains her awareness of the developments in the fields in which she publishes and teaches.

#### VII. Critical notes and recommendations.

I have no critical remarks about the candidate. My recommendation is to continue its publication work in the fields in which she has already made contribution, as given the dynamically changing regulations and the increasing number of drugs for rare diseases, for oncological diseases, as well as vaccines, this type of analyses and research is extremely valuable for healthcare decision-makers.

#### VIII. General assessment of the candidate's compliance with the mandatory conditions and mandatory quantitative criteria and scientometric indicators under the Regulation on holding academic positions at the Medical University of Varna

Higher education field 7. Healthcare and Sport, Professional field 7.1. Medicine, subject Pharmacology and Pharmacotherapy (Drug Policy) for the needs of the Department of Pharmacology, Toxicology and Pharmacotherapy, Faculty of Pharmacy at the MU of Varna

Table 1. Minimum required points by group of indicators for different scientific degrees and academic positions

Group of indicators	Content	Professor	Assoc. Prof. Dr. Albena Zlatareva, MD
A	Indicator 1	50	50
B	Indicator 2	-	
C	Indicators 3 or 4	100	100
D	Sum of indicators 5 to 9	200	550: 230 (in the main list) + 320 (in the additional list),
E	Sum of indicators 10 to 12	100	230
F	Sum of indicators from 13 to the end	100	341.43

#### IX. Conclusion



The candidate **meets** the mandatory and specific requirements and the scientometric criteria set out in DASRBA and the Regulations of the Medical University of Varna for the academic position "Professor" and even exceeds them.

#### **V. Proposal to hold the post**

The materials submitted by the candidate in the competition show that Associate Prof. Dr. Albena Zlatareva, MD fully meets the requirements for the academic position "Professor", pursuant to the Law on Development of the Academic Panel in Bulgaria, its Implementing Regulations and the Regulations of the Medical University of Varna. The submitted scientific papers and evidence for the research work meet the quantitative and qualitative criteria and are of a high contribution nature. They testify for a long-term dedication to science and the problems of the fields in which the candidate has publications.

Documents certifying that the candidate is a proven specialist in practice and a number of scientific and practical achievements are submitted. On the basis of the documents submitted, as well as based on my personal impressions, I can confidently state that the candidate has the necessary qualification for pedagogical and methodological competence.

In view of the above, I give my positive evaluation of Associate Prof. Albena Zlatareva, MD in the competition and I propose that the esteemed Members of the scientific panel award Associate Prof. Albena Zlatareva, MD the academic position "Professor" in the higher education field 7. Healthcare and Sport, professional field 7.1. Medicine, subject Pharmacology and Pharmacotherapy (**Drug policy**)

**Prof. Dr Krasimir Gigov, MD,**

