

REVIEW

by **PROF. KANCHO TRIFONOV TCHAMOV, MD, PhD,**
Member of the scientific jury appointed by order No.RD-38-237/16.05.2022 of the
Rector of Sofia University "St. Kliment Ohridski"

REGARDING:

Competition for the occupation of the academic position "Professor" in Professional field 7.3. Pharmacy, Scientific specialty "Social medicine and organization of healthcare and pharmacy", in the area of higher education 7. Healthcare and sports, for the needs of the Faculty of Chemistry and Pharmacy (FHF) at Sofia University "St. Kliment Ohridski".

The competition announced in SG No.30 of 15.04.2022 following a decision of the Faculty Council of the Faculty of Chemistry and Pharmacy described in the protocol No.26/ 10.05.2022.

The sole candidate in the competition is Associate Professor Emil Ivanov Hristov, MD, PhD from the Faculty of Chemistry and Pharmacy of Sofia University "St. Kliment Ohridski".

1. BIOGRAPHICAL DATA AND CAREER DEVELOPMENT

Associate Professor Emil Ivanov Hristov, MD, PhD was born on 25.01.1966 in Pernik. He graduated in medicine at the Sofia University in 1993. He has acquired 3 medical specialties as follows: internal medicine (2000), clinical pharmacology and therapeutics (2000) and gastroenterology (2006). Since 1995, he has been a teacher of internal medicine at the Department of Internal Medicine of the University of Sofia - successively as an assistant (1995-2002), senior assistant (2002 - 2009) and chief assistant (2009 - 2014). He works at the Clinic for Therapy of Internal Medicine and Clinical Pharmacology at the MHAT "St. Ivan Rilski" Sofia (1994-2006). After defending a PhD Thesis (dissertation work) at the Faculty of Pharmacy of Medical University of Plovdiv on the topic "Analysis of some regulatory aspects of the drug safety of biotechnological and high-tech medicinal products and new active substances", he received the educational and scientific degree "Philosophy Doctor" (2013). In 2014, after a competition, he held the academic position of "Associate professor" in the scientific specialty "Social medicine and organization of healthcare and pharmacy" in the Faculty of Chemistry and Pharmacy at Sofia University "St. Kliment Ohridski". From 2010 - 2012, he was a member of a group for the preparation of curricula for the transformation of the Faculty of Chemistry into the Faculty of Chemistry and Pharmacy at SU "St. Kliment Ohridski" in the academic disciplines "Social Pharmacy and Pharmaceutical Legislation", "Pharmacoeconomics" and "Biopharmacy and Pharmacokinetics". Associate Professor E. Hristov, MD, PhD has extensive administrative and scientific-applied experience in the field of drug regulation and registration of adverse drug reactions (ADRs). He was the Chairman of the Commission on the Positive Drug List at the Council of Ministers (2003-2004), the Chairman of the Pharmacopoeia Committee of the Republic of Bulgaria at the Ministry of Health (2008-2009), Executive Director of the Bulgarian Drug Agency (BDA) at the Ministry of Health (2004-2009). He was an expert in a number of expert councils and commissions at the Council of Ministers and the Ministry of Health of the Republic of Bulgaria. He was the responsible editor of the magazine "Journal of clinical medicine" and a member of the editorial board of the magazine "Drugs Bulletin".

His expert and applied activity in the field of drug policy and drug regulation in the structures of the European Union is impressive and related with participation in the Management Board of the European Medicines Agency, the Pharmaceutical Committee of the EC of the EU, The Heads of Medicines Agencies in the EU, etc.

The candidate is fluent in written and spoken English and Russian.

The synthetically presented information about the career development of Assoc. Prof. Emil Hristov, MD, PhD shows prominent and institutionally evaluated organizational and management qualities, hard work and purposeful pursuit of academic affirmation and development.

2. SCIENTIFIC OUTPUT OF THE CANDIDATE

Associate Professor Emil Hristov, MD, Phd participates in the competition with 62 real scientific publications, which are not included in the procedures for acquiring the Educational and scientific degree "Philosophy Doctor" and for occupying the academic position "Associate professor". In accordance with the requirements, in case of the absence of a published monograph work, the candidate should presents 10 scientific publications in journals that are referenced and indexed in world-renowned databases with scientific information. The overall scientific output of the candidate includes:

- PhD thesis: "Analysis of some regulatory aspects of drug safety of biotechnological and high-tech medicinal products and new active substances". (2013)
- Contributions to textbooks and teaching aids - 3 items (I-1-3)
- Published chapters in collective monographs: 12 items (II- 1-12)
- Publications in scientific journals, referenced and indexed in world-famous databases with scientific information - 27 items (III 1-27)
- Publications and reports published in non-refereed peer-reviewed journals or published in edited collective volumes – 20 items (IV)
- Participation in scientific projects – 5 items
- Management of scientific projects – 3 items
- Participation with reports at scientific forums - 24 items, of which 4 were presented at international forums.

In the mentioned publications, Assoc. Dr. E. Hristov, Ph.D. is first author in 17(27.4%), second author in 15(24.2%), third and subsequent author in 30(48.4%) of the presented scientific publications. The candidate's scientific output has been published in authoritative Bulgarian and foreign journals and anthologies. The dynamics of the candidate's publication activity by year is evenly distributed over time, which is evidence of systematic and purposeful scientific and career development.

3. MINIMUM REQUIRED POINTS FOR OCCUPYING THE ACADEMIC POSITION "PROFESSOR" IN PROFESSIONAL FIELD 7.3. PHARMACY (FACULTY OF CHEMISTRY AND PHARMACY AT SOFIA UNIVERSITY "ST. KLIMENT OHRIDSKI")

A group of metrics	Required number of points	Number of points scored by the candidate
Indicator A	50	50
Indicator B	100	121
Indicator Γ	200	630,9
Indicator Д	100	905
Indicator E	100	430
Indicator Ж
Total points	550	2136,9

Evidence of compliance with the minimum requirements of SU "St. Kliment Ohridski" show a total number of points from all indicators - 2136.9, which significantly exceed the minimum requirements of the Faculty of Chemistry and Pharmacy for occupying the academic position of "Professor". The assessment of compliance with the minimum requirements was made on the basis of the presented list 2014-2022 after the occupation of the academic position "Associate professor".

4. Thematic focus and scientific contributions

In accordance with the requirements, instead of a published monographic work, the candidate presents 10 scientific publications in publications that are referenced and indexed in world-renowned databases of scientific information. The analysis of the thematic orientation and scientific contributions in this review is based on the list No. 3 (2014-2022) submitted for participation in the competition.

The scientific interests of Assoc. Prof. E. Hristov, MD, PhD are multifaceted, finding realization in purposeful and sustainable scientific development and publication activity. The scientific production presented by the candidate corresponds to the direction of the announced competition, containing scientific-applied and theoretical contributions, thematically grouped in the following directions:

4.1. Clinical Pharmacology, Therapeutics and Clinical Trials (17)

This thematic direction is one of the two most thoroughly developed in the research activity of Assoc. Prof. E. Hristov, MD, PhD, including the following 17 publications (№I-1,2; II-1; III-1,2,5, 7,8,13,16,17,18,20,21 and IV-4,5,11). Of these, 12 have been published in refereed and indexed world-renowned scientific information databases, 3 in peer-reviewed journals, and 2 in collective monograph chapters. The studies of Assoc. Prof. E. Hristov, MD, PhD in this field are multifaceted and contain a rich set of scientific evidence obtained with the use of adequate methods and targeted interventions for the analysis of clinical trial results, new therapeutic approaches and methods for monitoring of biological products. This group of publications also includes own experience of using biological medicinal products (BLP) in autoimmune diseases - vasculitis, rheumatological diseases, etc.

Collective developments on drug utilization and rational drug use and therapy at the macro- and micro-level for specific therapeutic classes and for the drug market are presented. Scientific and applied contributions are made by the analyzes of existing possibilities for the entry of BLP into clinical practice, the therapeutic algorithms for their application, the issues of substitutability, switching and interchangeability, the appearance of adverse drug reactions. In this direction, the medicinal product utilization and rational drug use in the treatment of essential hypertension in Bulgaria was studied by using quantitative and qualitative measures at the national level. An applied contribution is the study of the morphometric characteristics of ruptured and unruptured aneurysms in a series of surgically treated patients with multiple intracranial aneurysms.

The results of the following studies have a contributing character in this direction:

- research on rational pharmacotherapy with biological products;
- the development of drug utilization and rational drug use for specific therapeutic classes (rheumatic diseases, arterial hypertension and vasculitis);

- the analysis of the availability and affordability of BPLP containing monoclonal antibodies and their utilization in Bulgaria;

The scientific production of the candidate in this thematic direction has an original character, being distinguished by the innovativeness of the methodological tools used and the originality of the obtained results with theoretical and applied contributions.

4.2. Pharmacovigilance and counterfeit medicinal products (12)

This thematic direction includes 12 real publications (No.III-5,6,9,10,11,12,15,19, and IV-3,15,17,32), the predominant number of which are interdisciplinary. 8 have been published in refereed and indexed world-renowned scientific information databases and 3 in peer-reviewed journals. The specificity of the candidate's scientific production in this direction is determined by the focus on researching priority aspects of drug safety, pharmacovigilance, regulatory and significance and its practical application as an obligation of state institutions, as well as a commitment of pharmaceutical manufacturers and a partnership with medical specialists and patients.

Studies conducted with the participation of the candidate aim to prove: the clinical responsibility of the pharmacist for the early detection of adverse drug reactions (ADRs); the type, frequency, severity, and location of ADRs that occurred during biological treatment; ADRs in patients with arthritic diseases treated with biologics, etc. The place and importance of the pharmacist in pharmacovigilance, active work with patients, as the main duty of pharmacists, is presented. Some deontological aspects of the pharmaceutical and medical professions related to pharmacovigilance, its regulatory importance and practical application are analyzed.

Developments in the field of counterfeit medicinal products are focused on: research and systematization of the Bulgarian experience in this field; analysis of cases of counterfeit medicinal products found on the Bulgarian market; analysis of the legislation in force in our country; presentation of scientifically motivated proposals for regulatory changes. The results of the study conducted in Bulgaria (according to Directive 2011/62/EU) for the practical introduction of serialization and verification include: development and presentation of an original algorithm for inclusion in the serialization and verification system; found a high level of lack of information among pharmacists about the presence of new regulatory requirements; insufficient knowledge of the practical challenges facing their pharmacy practices.

Contributory character in this rule are:

- studies on the type, frequency, severity and localization of ADRs that occurred during treatment with biologics in certain diseases;
- studies on the role and functions of the pharmacist in ensuring pharmacovigilance;
- the analyzes regarding: the presence of counterfeit medicinal products on the Bulgarian pharmaceutical market; the system for serialization and verification of medicinal products and the level of awareness of pharmacists about the new regulatory requirements.

The results of these studies are characterized by precision of the information obtained and causality.

4.3. Drug policy and Regulatory affairs (11)

This multi-faceted thematic direction includes 11 publications (№II-12, III- 14,23,24,25,26 and IV-8,10,16,32,40) of which 5 are published in refereed and indexed in world-famous databases

of scientific information, 5 in peer-reviewed journals and 1 in a collective monograph chapter. The acquired education, professional experience, academic development and skills for managing structures and resources in the pharmaceutical sector and public health allow Associate Professor Emil Hristov, MD, PhD to approach the researched impacts, processes and policies in an interdisciplinary and non-standard way.

A major emphasis in the candidate's studies is placed on: the causal relationship between priority problems, tools and goals of drug policy; the legal and normative regulation of pharmacy practice in our country; methods for assessing patient satisfaction with the quality of pharmacy services provided; analysis of legal and illegal practices in hiring pharmacy students for temporary work in the pharmaceutical sector; analyzes of foreign practical solutions for the pharmacist's role in the conditions of a pandemic crisis. The practical steps in the implementation of European legislation in the field of drug regulation, the national drug policy, the tasks before regulators and the pharmaceutical industry, the benefits for the system and citizens, as well as the national specificity of these processes are analyzed.

In the health policy aspect, the mechanisms for synchronizing the national drug legislation of the countries in the process of joining the EU have been studied, with an emphasis on the Bulgarian experience, problems and successes.

Systematized data on the presence of an unregulated labor market in the retail trade of medicinal products have been obtained for the first time in Bulgaria through surveys. Violations of drug and labor legislation were found (work without employment contracts, without job descriptions, unregulated pay, lack of health and social insurance and irregular working hours). A study with the participation of Assoc. Prof. Emil Hristov, MD, PhD reveals data on a high degree of lack of information among pharmacists about the presence of new regulatory requirements and related upcoming changes in the legal and regulatory framework for drug supply chain and pharmacy practice. In addition, reports from national and international scientific forums are presented, which discuss the mechanisms for synchronizing national drug legislation with the European one in the field of drug policy and drug regulation, as well as analyzes of current problems of regulatory practice, drug information and promotion .

In this direction, scientific contributions are made by:

- the analyzes of the national drug policy, regulatory practice and trends in the development of the pharmacy sector in our country;
- the scientific-applied analyzes and the obtained results for the functioning of the drug supply chain and pharmacy service system in Bulgaria;
- the original study of legal and illegal practices in the employment of pharmacy students on temporary work in the pharmaceutical sector;
- overview analyzes of the role of pharmacists and the participation of the pharmacy network in the fight against the COVID-19 pandemic.

The scientific production of Assoc. Prof. Emil Hristov, MD, PhD in this field presented with original developments, having scientific-applied and scientific-informative contributions.

4.4. Pharmacoeconomics and Health technology assessment (6) (No. I-3, III-3,4,27,IV-7,14)

This thematic field includes 6 real publications, of which 3 are published in scientific journals, referenced and indexed in world-renowned databases with scientific information and 3 in peer-reviewed journals. The contribution nature of the small number of publications with a high

utility coefficient is determined by the successful experience of establishing and developing scientific directions such as "Evaluation of health technologies" and "Pharmacoeconomics. In this regard, the co-authored first edition of the monograph "Fundamentals of Pharmacoeconomics" (2016) occupies a priority place.

In his studies, the candidate asserts the thesis of the four-component nature of health technology assessment, which includes: assessment of clinical effectiveness; economical analysis; budget impact assessment; and assessment of social, ethical and organizational impacts. The presented developments establish as a rule that the economic analyzes of health technologies related to medicinal products should be carried out according to the canons of a pharmacoeconomic study. In theoretical and applied aspects, Associate Professor Emil Hristov MD, PhD confirms the importance of budget impact analysis as a tool for forecasting the potential financial effects of the introduction of new technology in a healthcare system with limited resources. While economic analysis deals with the additional health benefits derived from investments in new health technologies, budget impact analysis examines their affordability in terms of net annual financial costs and the number of patients who would benefit from it.

The candidate's contributions in this scientific area are theoretical and methodical, including a theoretical justification of a new scientific direction; developed curriculum for a new discipline included in the Faculty of Chemistry and Pharmacy master's program; published study materials. The presented publications contain educational practices that are innovative in a methodological aspect, integrating academic training, scientific-research and applied-methodological activity with socially useful practice.

The scientific output of Associate Professor Emil Hristov MD, PhD has theoretical, applied and educational methodical contributions.

4.5. Hospital Management (11). (No. III-1-11)

11 published chapters of a collective monograph are included in this direction. (No. III-1-11) Publications are aimed at managing hospital resources, basic concepts and parameters, strategic planning, diagnostics, analysis and planning of key organizational factors (internal and external) in hospital care, priorities in hospital management are discussed on quality assurance of the management cycle and others. The analysis of the main structural problems of the Bulgarian health system served as a basis for formulating the priority guidelines for the successful management of the hospital. Of interest is the analysis of strategic and applied management, drug supply, rational drug therapy and the main tasks of the hospital manager in the conditions of a market economy. The scientific foundations of modern management are thoroughly studied with an emphasis on the tools for the management of hospital facilities, their infrastructural units and the operation of hospital pharmacies.

The publications presented in this thematic direction are collective developments of a contributing nature, including:

- results of micro-level studies on the application of modern methods of hospital management in the light of modern management theories and techniques;
- analyzes of the role of management and operational planning of the hospital facility and the hospital pharmacy for rational drug therapy in the hospital;
- analysis and planning of the key internal organizational factors in hospital care, priorities in the management of the hospital to ensure the quality of the management cycle;
- analyzes of the benefits of using modern management technologies such as strategic analysis, marketing analysis, system approach, system analysis, etc.

The candidate's publications in this direction are collective studies that have scientific-practical and informative contributions with the possibility of applying the obtained results.

4.6. History of Pharmacy and Pharmaceutical Care (5)

This field includes 5 scientific publications (III-22 and IV-12,13,24,41) of which 1 was published in a refereed and indexed edition in world-renowned databases with scientific information and 4 in peer-reviewed journals. The publications are aimed at studying in a historical aspect the models for organization, management and functioning of the system for drug supply and pharmacy service to the population in Bulgaria. The historical experience in the development of new concepts for pharmacy services focused on hospital and clinical pharmacy in the USA, as well as the role of the first female pharmacists in Bulgaria, were studied. The works presented in this direction contain theoretical and scientific-practical analyses, which chronologically trace the evolution of various aspects in the drug supply in our country. In this direction, original scientific contributions have been made by:

- analyzes of the quality of pharmacy services, as well as of the ethical, psychological and deontological aspects of the activity of pharmaceutical services in our country;
 - analyzes of pharmaceutical practice and training of pharmacists, as well as trends in the development of hospital pharmacies and clinical pharmacy in the United States;
 - the study on the first female pharmacists in Bulgaria, which has a significant scientific contribution related to the historical memory of Bulgarian pharmaceutical science and practice.
- The scientific production of the candidate in this direction has an original and contributing character and is distinguished by the use of adequate methodological tools and opportunities for application in the learning process.

5. Educational and teaching activity

The academic reference for teaching activity and study load issued by the Dean's Office of the Faculty of Chemistry and Pharmacy certifies that for the last 5 academic years from 2016/2017 to 2020/2021 Assoc. Prof. Emil Hristov, Md, PhD has a total academic load as follows: 2016-2017 academic year – 759.4 class; 2017-2018 - 641.2 class; 2018-2019 - 811.8 class; 2019-2020 - 882.7 class; 2020-2021 – 962.7 class. The workload includes: lectures and exercises; semester exams; study practices and thesis reviews. The classes conducted by the candidate include lectures and exercises with Educational qualification degree "Bachelor" and "Master", regular form of education in the following specialties: "Social Pharmacy and Pharmaceutical Legislation", "Pharmacoeconomics", "Pharmaceutical Care", "History of Pharmacy". Assoc. Prof. Emil Hristov, MD, PhD is the author and co-author of the study programs in the mentioned disciplines, systematically participating in their updating. He is the author of new curricula for elective courses in: "Clinical Medicine for Pharmacists" and "Fundamentals of Dermatology" for Masters in Pharmacy and "Cosmetic Legislation" for Masters in "Cosmetics and Household Chemistry", participating in their teaching. He is the co-author of a textbook on "Fundamentals of Pharmacoeconomics" and two textbooks. Participates in the teaching of Pharmacoeconomics to students under the Erasmus program, as well as in the teaching of English in the other academic disciplines.

6. Participation in scientific projects and supervision of doctoral students

The participation of Associate Professor Emil Hristov MD, PhD in the realization of five research projects under contracts financed by the Fund of Scientific Research of the SU "St. Kliment Ohridski (4 units) and the Fund of Scientific Research at Medical University - Sofia (1 unit),

three of which he is the head of. In two of the projects led by him, the participants are students. He is the scientific supervisor of five PhD students, two of whom defended their dissertations in 2022 on a PhD program in professional field 7.3. "Pharmacy" and the scientific specialty "Social Medicine and Organization of Healthcare and Pharmacy". He provided scientific guidance to 1 graduate student who defended his thesis in July 2022.

7. Citations and membership in scientific societies

The report on the citations of the publications of Associate Professor Emil Hristov MD, PhD presented by the Central Medical Library at the Medical University of Sofia until 2022 confirms that 20 citations were found in Bulgarian scientific publications and 18 citations in foreign scientific publications found in the databases of WEB OF SCIENCE, SCOPUS.

The candidate was the responsible editor of the "Journal of clinical medicine" magazine and a member of the editorial board of the "Lekarstven buletin" magazine.

Associate Professor Emil Hristov MD, PhD is a member of the following professional and scientific organizations:

- Bulgarian Society of Clinical Pharmacology and Therapeutics
- European Association of Clinical Pharmacology and Therapeutics
- Bulgarian Scientific Society of Gastroenterology

CONCLUSION

Associate Professor Emil Hristov MD, PhD, participated as the sole candidate in the current competition for awarding the academic position of "Professor". The assessment of the candidate's scientific output and educational activity shows: compliance with the scientometric criteria of the SU "St. Kliment Ohridski"; contribution nature of the presented scientific works; results of scientific and practical value; participation in the development of study programs and study aids; participation in scientific projects; compliance with the national minimum requirements for academic staff development.

In accordance with the provisions of the "Law on the Development of the Academic Staff in the Republic of Bulgaria" and the Regulations for the Development of the Academic Staff of SU "St. Kliment Ohridski" **I will vote positively**, recommending the members of the Scientific Jury to award Associate Professor Emil Hristov MD, PhD the academic position "Professor" in the area of higher education 7. "Healthcare and sport" in professional field 7.3. "Pharmacy" and the scientific specialty "Social Medicine and Organization of Healthcare and Pharmacy" for the needs of the Faculty of Chemistry and Pharmacy at Sofia University "St. Kliment Ohridski".

18/08/2022

Sofia

Reviewer:

Prof. Kancho Tchamov, MD, PhD