

## STATEMENT

Regarding the procedure for public defense of a dissertation and awarding the educational and scientific degree "Doctor" to **Master of Pharmacy Vladimir Antonov Atanasov**, PhD student in self-study at the Department of Physical Chemistry under the doctoral program "**Social Medicine and Organization of Health and Pharmacy**", in professional direction 7.3. "**Pharmacy**" of the Faculty of Chemistry and Pharmacy at Sofia University "**St. Kliment Ohridski**". The topic of the dissertation is: "Study of the role and participation of pharmacists in clinical trials of medicinal products".

Scientific leaders: Prof. Ilko Getov, PhD

Assoc. Prof. Emil Hristov MD, PhD

by Assoc. Prof. Sava Ognyanov, Faculty of Chemistry and Pharmacy, Sofia University "St. Kl. Ohridski", Chairman of the Scientific Jury, appointed by order № RD-38-627 / 22.12.2021 of the Rector of Sofia University "St. Kliment Ohridski"

Documents for participation in the competition are submitted within the legal deadline by Master of Pharmacy Vladimir Antonov Atanasov, PhD student in self-study at the Department of Physical Chemistry in the doctoral program "Social Medicine and Organization of Health and Pharmacy", in professional field 7.3. "Pharmacy" of the Faculty of Chemistry and Pharmacy at Sofia University "St. Kliment Ohridski". The scientific production for participation in the competition meets the minimum national requirements and is admitted for scientific evaluation. The statement attached by me is presented in accordance with the requirements of ZRASRB, PPZRASRB, of the Regulations on the terms and conditions for acquiring scientific degrees and holding academic positions at Sofia University "St. Kliment Ohridski", Chapter II. Acquisition of the educational and scientific degree "Doctor" and the scientific degree "Doctor of Science", Section III. Conditions and procedure for acquiring educational and scientific degree "Doctor".

### 1. Basic data for the dissertation

Master of Pharmacy Vladimir Antonov Atanasov presented his dissertation in a volume of 93 standard pages. The attached development is illustrated with 48 figures, 6 tables and 3 appendices. The literature presented by the Candidate contains 164 sources, of which 48 are in Cyrillic and 116 in Latin.

### 2. Relevance of the dissertation

Among the most important steps in the long and demanding process of developing new therapies are clinical trials. The development of science, as well as the development of knowledge and skills of master pharmacists, determine their ever-increasing role in various aspects of clinical trials. The need for additional research, conclusions and recommendations for the development and definition of opportunities for pharmacists in this field is also visible.

The research horizons in the dissertation of Vladimir Atanasov are relevant, they show us the gray areas in regulatory, legal and scientific aspects of the opportunities for participation of master pharmacists in clinical trials of medicinal products in humans.



The presented dissertation examines the important, but not fully studied and presented so far scientific, regulatory and scientific-technical rules and regulations determining the place, role, functions and participation of master pharmacists in clinical trials of medicinal products in humans.

The presented paper also analyzes the current regulatory framework for conducting clinical trials in Bulgaria, in the context of Bulgaria's membership in the EU.

### **3. Awareness of the problem**

Master of Pharmacy Vladimir Antonov Atanasov presented for defense a dissertation printed in a volume of 93 standard pages. The attached development is illustrated with 48 figures, 6 tables and 3 appendices. The literature presented by the Candidate contains 164 sources, of which 48 are in Cyrillic and 116 in Latin. The excellent theoretical training and knowledge of the scientific literature on the subject, as well as the ability to analyze and focus on critical aspects in it are visible.

### **4. Methodology, goals and tasks of the presented study:**

The theses, goals, tasks and methodology of the research of the PhD candidate Vladimir Antonov Atanasov are adequately formulated, clear, accurate and well-founded, illustrated and interconnected. The following research methodology provides an opportunity to achieve the tasks set by the PHD candidate in the dissertation. The methods and models used show that the PhD candidate is proficient in the subject. The conducted 3 prospective multicenter surveys allow us to combine the study of the existing regulatory framework with the opportunities and obstacles for the participation of pharmacists in clinical trials.

### **5. Significance, conclusions, results and contribution of the PhD candidate**

Master Pharmacist Vladimir Antonov Atanasov pointed out six main conclusions and made 5 contributions to science and practice related to the opportunities for participation of Master Pharmacists in clinical trials of medicinal products in humans. The conclusions are in harmony with the results obtained and correspond to the set goals.

The Candidate's contributions are in three directions.

#### **I. Scientific and methodological contributions:**

1. Development and testing of methodological tools - can be used in medical and social nested and targeted studies of the progress and development of the participation of pharmacists in clinical trials of medicinal products in the future.

#### **II. Scientific and applied contributions:**

1. The possibilities, advantages and disadvantages of the realization of pharmacists in conducting clinical trials of medicinal products in Bulgaria are presented.

. The conducted research allows the formulation of specific recommendations for the development of the training of students for the educational qualification degree "Master" in the professional field "Pharmacy" and can help the specialization and development of new areas for master pharmacists.

## II. Scientific and theoretical contributions:

1. For the first time a comprehensive and exhaustive regulatory, scientific and practical analysis of the role and participation of the pharmacist in clinical trials of medicinal products in Bulgaria has been made.
2. Basic guidelines and vision for the development of the profession of pharmacist and the need to acquire specific skills and competencies for participation and active role in conducting clinical trials have been formulated.

The content and quality of the abstract meets the requirements of the Regulations of Sofia University "St. Kliment Ohridski", that reliably and adequately reflect the main results of the study.

## Conclusion

The dissertation presented by Master Pharmacist Vladimir Antonov Atanasov on "Study of the role and participation of pharmacists in clinical trials of medicinal products" contains and presents significant results and original contributions, corresponding to the importance of the problem. The dissertation meets the requirements of the Law for the development of the academic staff in the Republic of Bulgaria and the Regulations for the development of the academic staff of Sofia University "St. Kliment Ohridski".

In this regard, as Chairman of the Scientific Jury, I will confidently vote in favor of awarding Vladimir Antonov Atanasov the educational and scientific degree "Doctor" in the field of 7. "Health and Sports" in the professional field 7.3. "Pharmacy" and the scientific specialty "Social Medicine and Organization of Health and Pharmacy".

23.02.2022  
Sofia

Author of the statement:

Assoc. Prof. Sava Ognyanov, PhD

