OPINION

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Regarding dissertation thesis for awarding the educational and scientific degree '**doctor**' in professional field **7.3 Pharmacy, doctoral program "Social medicine and organization of healthcare and pharmacy",**

PhD student: Master of Pharmacy **Vladimir AntonovAtanasov**

Form of doctoral studies: individual form of preparation

Department: Department of Physical Chemistry, Faculty of Chemistry and Pharmacy, Sofia University "St. Kliment Ohridski", Sofia

Topic: "Study of the role and participation of the pharmacist in clinical trials of medicinal products"

Scientific advisers: Prof. Ilko Nikolaev Getov, Ph.D.

Assoc. Prof. Dr. Emil Ivanov Hristov, Ph.D.

The presented set of materials is in accordance with the requirements for acquiring the educational qualification degree "Doctor" at Sofia University "St. Kliment Ohridski", Sofia according to the Act on Development of Academic Staff in RB and Regulations of Sofia University "St. Kliment Ohridski", Sofia.

The topic of the dissertation is the Study of the role and participation of the pharmacist in clinical trials of medicinal products.

The dissertation examines scientific, regulatory and scientific-practical rules and norms that determine the place, role, participation and functions of masters of pharmacy in clinical trials of medicinal products in humans.

The objectives of the dissertation are clearly stated and correspond to the title:

1. To analyze and identify the scientific, regulatory, scientific-applied and legal opportunities for pharmacists to participate in clinical trials, research and non-interventional studies of drugs, their functions and responsibilities, rights and obligations, and opportunities for professional realization.

2. To determine the actual participation of pharmacists in Bulgaria in clinical trials for the period 2016 - 2019, incl.

To achieve these goals, 5 tasks have been set. The goal and the set tasks are well, clearly formulated and interconnected.

The literature review is up-to-date, presented in 6 sections, which introduce us to the current knowledge of the problem and indicate the reasons for the present work. From the extensive and in-depth review it is evident that the doctoral student knows the issues addressed in the dissertation and demonstrates competence, depth on the issue.

The chosen research methodology allows achieving the set goals and obtaining an adequate response to the tasks set and solved in the dissertation. For the purpose and tasks in the set dissertation the

doctoral student has used the following methodologies: documentary analysis, content analysis and survey method.

1. An analysis of the content of the legislation at European and national level has been carried out in order to outline the current regulatory framework for conducting clinical trials of medicinal products in Bulgaria, in the context of Bulgaria's EU membership, and which allows masters in pharmacy to participate in clinical trials.

2. A "content analysis" of the Good Clinical Practice Guide was conducted to determine the possible functions of pharmacists in clinical trials.

3. Questionnaire method.

Three (3) prospective, longitudinal, multicenter survey studies were conducted in Bulgaria.

Survey № 1: Analysis of the readiness of hospital pharmacists to participate in clinical trials and non-interventional studies of medicinal products.

Survey № 2: Measuring the compliance of Principal Investigators in clinical trials to hire and work with hospital pharmacists in accordance with the requirements of the GCP and regulations

Survey № 3: Survey to assess the readiness of hospital pharmacists to participate in clinical trials and non-interventional studies of medicinal products among clinical trial associates / specialists (clinical monitors).

Data were processed using descriptive statistical methods with the software product SPSS version 19.

CHARACTERISTICS AND EVALUATION OF THE DISSERTATION

The dissertation consists of 93 pages and 3 appendices.

The dissertation is structured in 9 sections, as follows: introduction, literature review, purpose, tasks and methods, results of own research and analysis, main conclusions of the dissertation, contributions, used literature, applications.

It is illustrated with 48 figures, 6 tables and 3 appendices

164 contemporary literary sources are cited, in Cyrillic and Latin, most of them in Latin. The citations are reflected correctly and adequately, in accordance with the set goals and objectives of the dissertation.

Studies show that both in Bulgaria and worldwide, the role and participation of pharmacists in clinical trials of medicinal products have not been sufficiently studied, described and analyzed.

The scientific, regulatory and scientific-practical rules and norms determining the place, role, participation and functions of the Masters of Pharmacy can be defined as fundamental for the conduct and quality assurance of clinical trials of medicinal products in humans.

The main role of the pharmacist can be defined and should be focused on compliance with scientific quality requirements in the planning, conduct, reporting and reporting of clinical trials, production of research medicinal products, in accordance with good manufacturing and good laboratory practice, ethical norms and standards, the activities of the Ethics Committees, monitoring, preparation of the Researcher's Brochure, control, sanctions.

Pharmacists are recognized as the only medical professionals who have the necessary knowledge and competencies to ensure the storage and release of investigational medicinal products, can participate in all stages of documenting the processes, as well as in their monitoring and control.

The role of the pharmacist in conducting clinical trials is not specifically defined by the Rules of Good Clinical Practice, respectively it is necessary to be supplemented, but does not limit their participation in clinical trials.

The level of implementation of the changes in the legislation is unsatisfactory, as well as the readiness of the hospital pharmacists and members of the research teams to include and assign specific activities to the pharmacists.

The conducted research, which is specific for the purposes of the dissertation, shows that pharmacists are not ready for active and responsible participation in conducting clinical trials, they need specific training and acquisition of additional skills and competencies.

CONTRIBUTIONS AND SIGNIFICANCE OF DEVELOPMENT FOR SCIENCE AND PRACTICE

The contributions are divided into three parts: scientific-theoretical, scientific-methodical, scientific-applied.

Scientific and theoretical

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.

Scientific and methodological

1. Methodological tools have been created and tested - questionnaires that can be used in medical and social nesting and targeted studies of the progress and development of the participation of pharmacists in clinical trials of medicinal products in the future.

Scientific and applied

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

2. 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 to specialize and develop new areas of master pharmacists.

The doctoral student has presented 3 publications, two of which are in international journals.

He is the first author of two publications, which shows the personal participation and merit of the doctoral student in the dissertation research.

The publications are in editions referenced in SCOPUS and Web of science, which shows that they are the subject of wide popularization. The doctoral student has 3 participations with reports at scientific forums, 2 in Bulgaria with international participation and 1 abroad.

CONCLUSION

The dissertation of Vladimir Atanasov, Study of the role and participation of the pharmacist in clinical trials of medicinal products, contains scientific and applied results that represent an original contribution to science and meet all the requirements of the Law on the Development of Academic Staff in the Republic Bulgaria (ZRASRB), the Regulations for implementation of ZRASRB and the

respective Regulations of Sofia University "St. Kliment Ohridski", Sofia. The presented materials and dissertation results fully comply with the specific requirements of Sofia University "St. KlimentOhridski", Sofia.

The dissertation shows that the doctoral student mag. farm. Vladimir Antonov Atanasov has theoretical knowledge and professional skills in the scientific specialty by demonstrating qualities and skills for independent research.

In the view to the above, I confidently give **my positive** assessment and I propose to the Scientific Jury to award the educational and scientific degree "Doctor" of **Vladimir AntonovAtanasov** in a doctoral program in **"Social medicine and organization of healthcare and pharmacy ".**

22.02.2022 Reviewer: .....

Assoc. Prof. Daniela Grekova, Ph.D.