REVIEW

From: Prof. Valentina Boyanova Petkova-Dimitrova Ph.D., Vice-Rector for Science and Accreditation, Medical University - Sofia, member of the scientific jury, included by Order № RD-38-627 / 22.12.2021 of the Rector of Sofia University "St. Kliment Ohridski ”.

Subject: procedure for defense of a dissertation on the topic: "Study of the role and participation of pharmacists in clinical trials of medicinal products" in the field of higher education - 7. Health and Sports Professional field - 7.3 Pharmacy Scientific specialty "Social medicine and organization of Healthcare and Pharmacy ”by Master of Pharmacy Vladimir Antonov Atanasov, research supervisors: Assoc. Prof. Dr. Emil Hristov, Ph.D. and Prof. Ilko Getov, Ph.D.

Master of Pharmacy Vladimir Antonov Atanasov was born in 1991. In 2015 he successfully graduated from the Faculty of Pharmacy of the Medical University - Sofia and obtained a master's degree in Pharmacy. Three years later in 2018. he also obtained a second master's degree in Public Health and Health Management.

His career began as a "clinical research specialist" at Verum Clinical Ltd. After that he performed the same activity in GlaxoSmithKline, and since 2016 he has been a senior specialist in clinical research at HT Research BG.

The dissertation provided to me covers 86 pages and is structured as follows: Introduction - 3 pages, Literary review - 14 pages, Goals and objectives - 1 page, Materials and methods - 3 pages, Results of own research and analysis - 42 pages, Main conclusions from the dissertation - 1 page, Contributions - 1 page, References

- 14 pages, Appendices. The structure of the dissertation, as well as the presented set of materials on electronic media is in accordance with the Regulations on the terms and conditions for obtaining scientific degrees and holding academic positions at Sofia University and includes the following documents: Enrollment order, expulsion order, resume, diploma for higher education, dissertation, abstract, certificate of passed exams, declaration of authorship, reference for EOM doctor, plagiarism report, protocol for originality of the dissertation, statement of originality, instructions for verification of originality, order for scientific jury. All required documents are neatly arranged and in accordance with the requirements.

This 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 place of the pharmacist in the observance of the scientific requirements for quality in the planning, conducting, reporting and reporting of clinical trials, the production of research medicinal products, in accordance with the Good Manufacturing and Good Laboratory Practice, ethical norms and standards, the activities of the Commissions has been studied in great detail. on ethics, monitoring, preparation of the Researcher's Brochure, control, sanctions, etc., which makes the work modern and up-to-date.

The review part, as structured, traces the stages of conducting the clinical trial in the light of current European and national legislation, seeking the regulated participation of master pharmacists. The review provides a detailed analysis of research on the topic published so far, which proves the innovativeness of the chosen topic.

The summary of the review also shows the choice of further research in the dissertation, namely the lack of research on the role and participation of the pharmacist in clinical trials of medicinal products. This makes the chosen topic

original in nature for Bulgaria. The integrity and completion of the overview outlines the direction of further research.

Two goals and five main tasks have been formulated, which have been successfully carried out in the course of our own research.

The tools used include an analysis of the content of the legislation at European and national level 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 of pharmacy to participate in clinical trials; "Content analysis" of the Guide to Good Clinical Practice to determine the possible functions of pharmacists in clinical trials, as well as three prospective, longitudinal, multicenter surveys in Bulgaria. Through the variety of methods used, which are skillfully combined to achieve the goal, the main task of this dissertation was achieved - to analyze and identify scientific, regulatory, scientific and 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, determining the actual participation of pharmacists in Bulgaria in clinical trials for the period 2016 - 2019.

The obtained results are demonstrated in five main parts - analysis of the current regulatory framework regarding clinical trials and the participation of pharmacists in them; identify possible places for participation and professional realization of pharmacists in the various stages of clinical trials, in accordance with current applicable law; analysis of the readiness of hospital pharmacists to participate in clinical trials and non-interventional studies of medicinal products; study of the compliance of Principal Investigators in clinical trials to hire and work with hospital pharmacists in accordance with the requirements of the GCP and regulatory changes; assessment of the readiness of hospital pharmacists to participate in clinical trials

and non-interventional studies of medicinal products among clinical trial associates / specialists (clinical monitors). The results of the individual studies are interesting as stand-alone studies, but in their sequence and completeness represent a comprehensive analysis of the possibilities for the realization of master pharmacists in the various stages of clinical trials.

The formulated conclusions correspond to the set tasks, so that the doctoral student has fulfilled his set goals and tasks. The developed dissertation thesis outlines the conclusion that both in Bulgaria and worldwide, the role and participation of the pharmacist in clinical trials of medicinal products have not been studied, described and analyzed in sufficient detail. 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 standards 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 supplement, 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. Pharmacists are not ready for active and responsible participation in

conducting clinical trials, they need specific training and acquisition of additional skills and competencies.

The results of the dissertation have been published in six scientific articles.

Contributions that can be differentiated can be grouped as:

- 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.

- Contributions of scientific and applied nature

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 realization of Master Pharmacists.

- Contributions of a methodological nature:

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.

According to the scientometric report for fulfillment of the minimum national requirements, the applicant exceeds the required points.

In conclusion, the dissertation on the topic: "Study of the role and participation of the pharmacist in clinical trials of medicinal products" by Mag. Pharm. Vladimir Antonov Atanasov, developed with the right goals and objectives, using adequate methodological tools and reliable interpretation in the discussion of the results meets the requirements for obtaining the educational and scientific degree "Doctor". The proposed draft abstract fully reflects the essence of the work.

I accept that the work is an independent work of the dissertation student and I suggest to the honored members of the scientific jury to give their positive vote and to award a mag.. pharm. Vladimir Antonov Atanasov educational and scientific degree "Doctor".

23.02.2022 Reviewer:

Sofia / Prof. V. Petkova, DSc/