STATEMENT

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Subject: dissertation on the topic **„Administrative regulation of prices of medicinal products in Bulgaria“** by Vasil Chavdarov Tankov for obtaining the Educational and Scientific Degree „Doctor“ in field of higher education 3. Social, Economic, and Legal Sciences, professional field 3.6 Law, doctoral program „Administrative Law and Administrative Process“ at the Faculty of Law of „Paisiy Hilendarski” University of Plovdiv, with scientific supervisor Prof. Ivan Todorov, PhD.

DEAR MEMBERS OF THE SCIENTIFIC JURY

By order of the Rector of „Paisiy Hilendarski” University of Plovdiv No. RD-22-812 of 02.04.2025, I have been appointed to participate in the composition of the scientific jury as an external member for the defence of the Educational and Scientific Degree „Doctor“ in field of higher education 3. Social, Economic, and Legal Sciences, professional field 3.6 Law, doctoral program „Administrative Law and Administrative Process“. By decision of the scientific jury, I have been assigned to provide a statement in this procedure.

1. General notes

Vasil Chavdarov Tankov was enrolled as part-time doctoral student in the doctoral program „Administrative Law and Administrative Process“ at the Department of Public Law Sciences of the Faculty of Law of „Paisiy Hilendarski” University of Plovdiv in 2021. After completing his studies, he was dismissed with the right to defence.

In relation with the admissibility of the procedure, Vasil Tankov has submitted all necessary documents. The abstract correctly reflects the structure of the dissertation and presents the main contributions of the research. In addition to his dissertation, the doctoral student also presents 4 publications, including 1 article and 3 studies. After reviewing the materials submitted for the procedure, I conclude that the candidate meets the minimum requirements of the Development of Academic Staff in the Republic of Bulgaria Act (DASRBA), the Regulations for the DASRBA implementation, and the relevant internal rules of „Paisiy Hilendarski” University of Plovdiv.

2. General characteristics and evaluation of the dissertation

The dissertation presented in this procedure is 202 pages long and includes an introduction, four chapters, a conclusion, a bibliography, and appendices. The work has a contributory significance for the Bulgarian legal doctrine, as it represents the first study of its kind dedicated to the legal administrative regime for regulating the prices of medicinal products in Bulgaria. The author has argued the relevance and significance of the topic, outlining the subject, objectives, methodology, and structure of the work.

In the first chapter of the dissertation, the doctoral student traces the historical development of the analysed matter from 1879 to the present day. A contributory aspect in this chapter is the

skilful combination of theoretical analysis with historical context and analysis of the legal framework, which is of particular importance for understanding the specificities in the field of drug pricing in Bulgaria. Of interest is the table added in the appendix, which systematizes key information about the reviewed legal acts and illustrates the conducted review. By consistently and thoroughly analysing the normative acts, the author identifies the continuity of basic principles that are integrated into the modern mechanism of the Positive Drug List. Special attention is brought to the administrative bodies with sectoral special competence, providing a comprehensive overview of their structure and functions over the years.

In the second chapter, the doctoral student conducts a detailed analysis of the concept of a medicinal product, using numerous definitions – from early pharmacological sources to modern legal definitions contained in national and European legislation. A key aspect is the differentiation of medicinal products for human medicine from similar but different products (food supplements, medical devices, veterinary medicinal products), which is important for the application of the relevant legal administrative regime. I consider this approach to be correct for the subsequent analysis of the topic. In addition, the chapter also classifies medicinal products based on their legal administrative regime. The author examines in detail the subjects involved in the procedures for price recording and regulation of medicinal products. Based on a thorough review, the author reasonably criticizes the provisions of Article 26(1) and Article 73(1) of the Medicinal Products in Human Medicine Act, examining the conditions and limitations for the subjects who can be holders of a marketing authorisation (MAH) upon initial issuance and subsequent transfer of rights to the marketing authorisation. Of interest is the grouping into main categories of the functions of the other main subject in the procedure – the National Council on Prices and Reimbursement of Medicinal Products (NCPRMP). This systematisation contributes to a clearer understanding of the diverse competence of the NCPRMP in the area under consideration.

Vasil Tankov's research continues with the Positive Drug List (PDL), examining its essence, structure, and functions, as well as the applied models of reference pricing. After reviewing the doctrinal views on the legal nature of the PDL, the author's vision of the PDL as a „kind of legal and technical mechanism for disclosure and mutual regulation of the prices of medicinal products" stands out as a contributory moment.

Chapter three is dedicated to the legal framework for the formation and recording of prices of the three types of medicinal products. For this purpose, a review and analysis of the legally established elements that form the basis of their pricing are presented. The doctoral student challenges the chosen legislative approach for identically structuring the pricing of prescription medicinal products, regardless of their inclusion or non-inclusion in the PDL.

This chapter systematically traces the stages of the procedure for regulating and recording the prices of medicinal products. A contributory aspect is the critical analysis that identifies the lack of explicit regulation for key aspects such as the admissibility check, and the content and requisites of decisions for including a medicinal product in the PDL and for approving its price. Significant emphasis is placed on the rights of interested parties and the need for their timely notification for the initiation of the procedure. In this regard, the author proposes *de lege ferenda* improving the publicity and protection of their rights and legitimate interests by creating a public register of proceedings initiated before the NCPRMP.

The author examines the regulation for price changes, criticizing the complexity and verbosity of the relevant provisions. Justifiably highlighted as a problem is the obligation under

Article 262^3 of the MPHMA to notify third parties of NCPRMP decisions on price changes even before they enter into force, which creates legal uncertainty for the addressees of the notification. In this regard, the author also proposes the creation of a public register of NCPRMP acts with real-time notation of their status (with preliminary enforcement allowed, appealed, entered into force, etc.). Next, the doctoral student also examines the procedure and consequences of deleting the price of a medicinal product. Vasil Tankov reasonably proposes abolishing the obligation to declare in the absence of price changes for medicinal products included in the PDL and replacing it with an entirely ex officio procedure that would speed up the process and engage the MAH only when genuinely necessary – when a lower price is found and their statement is required before a decision is made. A valuable contribution is the comparative legal analysis of the European legislation, presenting the specifics in the investigated matter in several specific countries, as well as the US model for regulating the prices of publicly funded medicinal products.

The fourth chapter deeply examines the legal nature of acts regarding the registration of medicinal product prices. For this purpose, the author analyses the decisions by which the NCPRMP approves and registers, amends, or deletes the price of a medicinal product, or issues an explicit refusal to do so, relating them to the legal classifications established in the doctrine and drawing corresponding conclusions about their specific features. A contributory aspect is the comprehensive consideration of issues related to the entry into force and preliminary enforcement of NCPRMP decisions. The part of the work concerning judicial and administrative appeals of NCPRMP decisions deserves attention. A key point in the analysis is the author's view that appealing before the Transparency Commission reveals the characteristics of a judicial activity of a special jurisdiction. This contribution includes a historical and comparative overview of the admissibility of special jurisdictions according to the current constitutional model, as well as a revised reading of the research on the matter by Acad. Staynov and Prof. Stalev. In this sense, the characteristics of the judicial activity of administrative bodies are identified and thoroughly examined. Next, the author aptly distinguishes between the procedure for contesting before a special jurisdiction and before a higher authority. Of contributory significance is the subsequent analysis of the status and nature of the Transparency Commission's activities from the perspective of the normative regulation and case-law, as well as the attribution of the characteristics defining special jurisdictions to its activities. As a result of the review, the author reaches conclusions of important practical relevance and formulates proposals for improving the current regulation.

The challenges identified by the author are summarized in the conclusion of the work and presented as constructive *de lege ferenda* proposals for improving the normative framework.

I believe that Vasil Tankov's submitted dissertation contains a clearly formulated research topic and in-depth analysis, characterized by originality and a number of scientific and applied results of a contributory nature. I recommend that the author continues his scientific research in the field and makes his work accessible by publishing it as a book, while also paying attention to the technical formatting of the individual parts of the dissertation, to the referencing of the appended material in the relevant places, and to the more in-depth integration of the cited legal sources, which will contribute to the greater precision of the research.

3. Conclusion

In the view of the above and considering the legal requirements, **I confidently give my positive evaluation and propose to the scientific jury to award the educational and scientific**

degree „Doctor“ to Vasil Chavdarov Tankov in field of higher education 3. Social, Economic, and Legal Sciences, professional field 3.6 Law, doctoral program „Administrative Law and Administrative Process“ at „Paisiy Hilendarski“ University of Plovdiv.

May 23, 2025

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