

## RECENSE

by Prof. Darina Zinovieva, PhD, Faculty of Law, Plovdiv University

on a dissertation on: “ ADMINISTRATIVE REGULATION OF PRICES OF  
MEDICINAL PRODUCTS IN BULGARIA”

by Vasil Chavdarov Tankov

for acquiring the educational and scientific degree of Doctor in the  
professional field 3.6. Law, Doctoral Program "Administrative Law and  
Administrative Process" in Plovdiv University "P.Hilendarski", with  
academic supervisor: Prof. Ivan Todorov

### 1. GENERAL NOTES

I have been appointed as a member of the scientific jury by Order No  
RD-22-812 of 2.04.2025 of the Rector of the Plovdiv University ‘P.  
Hilendarski’.

Vassil Tankov graduated in law in 2005 in the FL of Sofia University. He  
has specializations related to mediation and is entered in the register of  
mediators at the Ministry of Justice. He is also registered as an industrial  
representative in the Patent Office. He also taught at a private  
Eurostandard school. Since 2006 he has been a lawyer. Since 2021, he  
has been a doctoral student at the Faculty of Law at the University of  
Plovdiv ‘P. Hilendarski’ and, after completing his doctoral studies, he was  
granted the right to defend himself.

Vasil Tankov meets the minimum national requirements under Article 2b(2) and (3) of the ZRASRB, which is also reflected in the minutes of the first meeting of the scientific jury.

The author, in addition to the dissertation, additionally presents four publications - one article and three studies, one of which is in co-authorship. The presented autoreferate is comprehensive and correctly reflects the contributing elements of the study.

## 2. ANALYSIS AND CONTRIBUTIONS OF DISSERTATIONAL LABOUR

The presented dissertation is written on a topic on which there is no other scientific legal work. The topic is analyzed mainly from its economic aspects, but a legal analysis of pricing, legal mechanisms and the legal system of administrative bodies is lacking in this detail and comprehensiveness. The choice of this topic represents a contribution to our legal doctrine.

The content of the work is divided into an introduction, four chapters and a conclusion.

The author in the Introduction justifies the research approaches used, which I believe are consistent with the purpose of the study. Historical, comparatively-legal, systematic legal method of research is used, and the objectives of the research are indicated. The author also justified the actuality of his work faithfully and objectively.

In Chapter One, entitled 'Historical overview of the evolution of the regulatory regime and registering the prices of medicinal products in Bulgaria', Vasil Tankov makes a retrospective analysis of the regulations regulating the trade in medicinal products from the nineteenth century to the present. The analysis of each normative act is in-depth, showing the

state's view on the public relations related to the marketing of medicines in the state. Thus, the author concludes that the principles contained in the first legislative act of 1879 still work today, but through the mechanisms of action of the so-called positive drug list. The conclusion is important as it reveals the sustainability of drug pricing mechanisms. Also of interest is the part of this chapter concerning the historical analysis of administrative bodies with competence in pricing as well as those with competence in the management of the medicinal sector in the healthcare sector.

Chapter Two deals with the analysis of the object of pricing - the medicinal product, and a positive assessment should be made of the distinguishing analysis of the concept of a medicinal product and similar objects such as food supplements, veterinary medicinal products, etc. In this chapter, C. Tankov also skilfully analyses the entities with competence in the legal regulation of the prices of medicinal products in Bulgaria.

With these comparative analyses, the author shows the differences in their legal characteristics, and hence the need to control the prices of medicinal products. The center of this part of the work is the detailed legal analysis of the positive drug list as a legal institute and the conclusions that the author draws and which have a pragmatic application.

The procedural legal study of the method of formation and registration of the prices of medicinal products is of significant importance in Chapter Three.

The details in which the author enters are important, such as separating the pricing of medicines from the positive list from the pricing of medicines not contained in it. Separately, V. Tankov analyzed the specifics of the two types of medicinal products - those that are subject

to medical prescription and those that are sold without a medical prescription. The conclusions related to the marginal price as a legal means of access of the population to treatment through medicinal products are of significant importance.

This chapter systematically and logically examines all stages of regulatory and production price recording. In addition to the standard stages, such as the initiative to initiate proceedings, the admissibility and regularity of the legal initiative concerned, the analysis of additional procedural steps, such as declaring no change in price, should be highly appreciated.

medicinal products included in the positive list. I appreciate the author's approach to analyze the European legislation and the peculiarities of its implementation, as well as the analysis of the legislation and practice in the USA. The conclusions are justified logically and comprehensively.

In Chapter Four, Vassil Tankov focuses on the acts issued by the competent authorities for registering the prices of medicinal products. It divides these acts into species, according to the authority that issues them and makes an analysis and corresponding conclusions about their peculiarities related to their legal nature. I appreciate his analysis of the manner of their entry into force and the peculiarities of their preliminary implementation. In a separate part, the author examines the appeal proceedings against the acts of registration and regulation of prices

The analysis of Vassil Tankov on the status of the Transparency Committee of the Council of Ministers is important. His reflections on whether the Commission is a special jurisdiction or only an administrative body are of significant importance, as he reaches conclusions of an important applied nature.

At the end of this chapter, the author analyzes the administrative and criminal liability and the criminal liability provided for in our legislation for

violations related to pricing and, in particular, for non-compliance with the decisions of the relevant administrative authorities.

The conclusion summarizes the conclusions of the scientific research and the proposals for optimizing the legislation.

Throughout the dissertation, examples from the case law of different courts in Bulgaria have been used. An interesting approach is to complement the study with targeted applications at the end.

I consider a number of proposals *de lege ferenda* to be appropriate and well-founded. I particularly appreciate the proposal concerning the texts of Articles 26(1) and 73(1) of the ZLPHM on pages 167-168 of the dissertation.

In summary, the author has managed to build a comprehensive picture of the complex legal regime of the pricing of medicines in our country, of the administrative procedures for issuing acts and their contestation, in relation to the topic.

His knowledge of administrative law and procedure is very well connected with the special knowledge in the field of legal regulation of medicinal products.

This knowledge is also evident in the relevant critical analyses and good proposals for optimizing our legislation.

## CRITICAL NOTES

I recommend the author to publish the work in a book, adding more attached material, as the work has a very strengthened legal-practical focus.

## CONCLUSION:

In view of the above and the legal requirements, I give my positive assessment and recommend to the scientific jury to vote positively for the award of the scientific degree "Doctor" to Vasil Chavdarov Tankov for acquiring the educational and scientific degree "Doctor" in the professional field 3.6. Law, Doctoral Program "Administrative Law and Process" in Plovdiv University "P.Hilendarski"

19 April 2025

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