

## OPINION

By Assoc. Prof. Konstantin Vasilev Pehlivanov, PhD, Faculty of Law, Plovdiv University "Paisii Hilendarski"

on a dissertation thesis: "Administrative Regime of Regulating the Prices of Medicinal Products in Bulgaria" by Vasil Chavdarov Tankov

for acquiring the educational and scientific degree "Doctor" by are of higher education 3. Social, economic and legal sciences, professional field 3.6. Law, Doctoral Programme "Administrative Law and Administrative Process" at Plovdiv University "Paisii Hilendarski", tutored by Prof. Ivan Todorov Ph.D.

I present this opinion as a member of the scientific jury appointed by Order of the Rector of the University of Plovdiv No RD-22-812 of 2.04.2025 to conduct a procedure for the acquisition of a PhD degree.

My conclusions on the admissibility of the procedure are: the applicant for the acquisition of the PhD degree has submitted the required set of documents, the abstract is in two languages and accurately reflects the structure of the dissertation, the applicant meets the minimum national requirements under Article 2b(2) and (3) of the Promotion of Academic Staff in Republic of Bulgaria Act, which is also reflected in the minutes of the first meeting of the scientific jury. In addition, an article and three studies are presented, one of which is co-authored. In conclusion, I find the dissertation presented admissible for consideration on the merits before a scientific jury.

My conclusions on the substance of the procedure are:

A scientific paper is presented on a topic that has not been studied independently so far. The scientific work itself has novelty and contribution.

The scientific work consists of an introduction, four chapters and a conclusion. The introduction sets out the scientific methods used, which I find justified - historical, comparatively-legal, systematic method of research. The objectives of the scientific development are also indicated.

In Chapter One, entitled 'Historical review of the development of the regime for regulating and registering the prices of medicinal products in Bulgaria', the dissertator has made a historical analysis of the legal acts that regulate the trade in medicinal products to date, starting from the first little-known act, the Provisional Rules for the Structure of Medical Management in Bulgaria of 1879. A thorough analysis of the legal acts in their sequence has been made. It has been concluded that the principles contained in the first normative act of 1879 work now through the mechanisms of action of the so-called positive drug list, the distant prototype of which is the preiscurant. Of particular interest is also the part of that chapter relating to the historical analysis of the administrative bodies with competence in the pricing and management of the medicinal sector in the healthcare sector. A thorough and conscientious study of the management of the portfolio since the emergence of the modern Bulgarian state has been made here, including subordination, numerical staff, members of the law bodies, etc., which is undoubtedly a valuable contribution to our doctrine, since such a detailed study has not been conducted so far. Of particular interest to me was the study of the moment of transition to a market economy 1989-1991.

Chapter Two, entitled 'Subject matter, subjects and mechanism in the registration and regulation of prices of medicinal products in Bulgaria', analyses the object of pricing – the medicinal product – and positively assesses the differential analysis of the concept of a medicinal product and similar products, such as food supplements, veterinary medicinal products, etc. The competence of the public authorities in the portfolio is also analysed. The concept of a medicinal product has been studied in depth and interdisciplinarily, also drawing attention to the achievements of EU law. The types of medicinal products are distinguished (pp. 46-48), laying the basis of a scientific apparatus for further detailed study of matter in a systematic order. Possible marketing authorisation holders were also analysed in the same way.

A significant point is the detailed legal analysis of the positive drug list as a legal institute and the analysis of the National Council on Prices and Reimbursement of Medicinal Products as a central state body with its specifics. The author examines the conceptions in the theory and rightly notes that the opinions about the positive drug list are polar (p. 60). He justifies its view of a "legally and technically appropriate mechanism for the disclosure and regulation of the prices of medicinal products".

Chapter Three, 'Establishment and registration of the prices of medicinal products', I consider to be the strongest and most contributing and core of the dissertation. It focuses on researching the process by which the price of medicinal products is justified and recorded. 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, the specifics of the two types of medicinal products - those subject to medical prescription, for which a prescription is not needed, are analyzed. I highly appreciate the conclusions relating to the price cap as a legal means for the population to access treatment through medicinal products. A relevant analysis is made of similar procedures in other countries.

Systematically and in good logical connection, all stages of the regulatory procedure and the production of price recording are examined. In addition to the steps specific to each administrative procedure, such as the initiative to initiate the procedure, the admissibility and regularity of the legal initiative concerned, the analysis of additional procedural steps, such as declaring the absence of a change in the price of medicinal products included in the positive list, should be highly appreciated. 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 US. The conclusions are justified logically and comprehensively.

In Chapter Four, entitled 'Legal nature of price-registration acts for medicinal products. Entry into force and contestation. Administrative and Criminal Liability for Non-Compliance', the author analyses the acts issued by the competent authorities for registering the prices of medicinal products. He divides these acts into species, starting from 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. A strong and important part is the appeal procedure against the acts of registration and regulation of the prices of medicinal products in administrative and judicial proceedings.

I find the analysis of the status of the Transparency Committee at the Council of Ministers and the reflections on whether it has the characteristics of a special jurisdiction to be particularly useful. The author touches on an old dispute in our law and I find his remarks justified and

interesting from a general theoretical point of view. A particularly good impression is the study of all possible literature in our country and the reflection of the views in it. The study of the aspect is also useful: what is the point, what is the practical benefit of the existence of the special jurisdiction. In the same sense is one of the attached articles, which I highly appreciate.

Practically strong and contributing part is the analysis of administrative and criminal liability, as well as criminal liability for violations related to pricing.

I consider the proposals made *de lege ferenda* to be well founded.

I hope that the dissertation will be published in a book that will have a pronounced practical significance and will enrich our doctrine, in which there has been no such research so far. The style is at a high level, easy to read and perceive. Appendices have been added to the dissertation that illustrate the author's searches and facilitate the reader's inquiries, they would be a very successful addition to the work when publishing.

In conclusion: in view of the above and the legal requirements, I give my positive assessment and find that, in view of the quality of the dissertation entitled 'Administrative Regime of Regulating the Prices of Medicinal Products in Bulgaria', the scientific jury should award the educational and scientific degree 'Doctor' to Vasil Chavdarov Tankov by area of higher education 3. Social, economic and legal sciences, professional field 3.6. Law, Doctoral Programme in Administrative Law and Procedure.

Drafted the opinion

(Assoc. Prof. K. Pehlivanov)

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