REVIEW

From: Prof. Veselina Kanatova-Buchkova PhD - Institute for State and Law at the Bulgarian Academy of Sciences

Subject: dissertation for awarding educational and scientific degree **"Doctor"** in doctoral program "Administrative Law and Administrative Procedure" at Plovdiv University "Paisii Hilendarski"

Reason for submitting the review: participation in the scientific jury for defence of dissertation in accordance with Order No RD-22-812/02.04.2025 of the Rector of Plovdiv University 'Paisii Hilendarski'

Author of the dissertation: **Vasil Chavdarov Tankov**

Subject of the dissertation: **"Administrative Regime Regulating the Prices of Medicinal Products in Bulgaria"**

Scientific supervisor: Prof. Ivan Todorov, PhD

I. Information about the dissertation.

The PhD studied under a doctoral program at the Department of Public Law at the Faculty of Law of Plovdiv University 'Paisii Hilendarski' in the doctoral program 'Administrative Law and Administrative Process' as a part-time doctoral student.

He has completed his legal education at Sofia University "Sv. Kliment Ohridski' in 2005, having previously obtained a bachelor's degree in social pedagogy at Sofia University 'Sv. Kliment Ohridski'. Since 2006 he has been an attorney-at-law at the Sofia Bar Association. He was enrolled as a doctoral student at Plovdiv University "Paisii Hilendarski" in 2021.

For the period of the doctorate, he has fulfilled all the requirements that are set out in the individual plan.

II. General characteristics of the dissertation presented.

The thesis complies with the requirements of Art. 27 of Regulation on Implementation of the Promotion of the Academic Staff in Republic of Bulgaria. It is structured in four chapters, in a total volume of 202 pages, including the introduction, content, list of used literature and applications. The bibliography includes 40 sources in Bulgarian and 2 sources in a foreign language.

The dissertation is structured according to the subject of study. The topic is topical with a high degree of practicality, in view of the approach adopted by the author of distinguishing medicinal products from similar products, on the one hand, and on the other, highlighting the specific features in the administrative procedures for registration and regulation of their prices.

The first chapter provides a historical overview of the emergence of the legal regulation of drug prices, and successively reviews regulations dating back to the 19th century. It is pointed out that the principles laid down in the only provision of Article 165 of the Sanitary Act - the first normative act that deals with the issue of the prices of medicinal products, are actually found today in the system built through the mechanism of the Positive Medicines List. Attention is drawn to a kind of rehabilitation institute regarding the prohibition to close a pharmacy because of the apothecary's debts, introduced in the Public Health Act of 1929. With the adoption of the Medicinal Products and Pharmacies in Human Medicine Act 1995, adopted after the changes in the socio-political life in the country, a simplified mechanism of determining the prices of medicinal products is introduced, based on one factor - the cost of production of the product concerned, without assessing the prices in neighbouring or other European countries, as was applied in the pricing mechanisms of the first half of the century. It appears that, for the first time, the adoption of the Medicinal Products and Pharmacies in Human Medicine Act 1995 draws a distinction between state regulation of the prices of prescription medicines and registration of non-prescription medicines. Also, for the first time, with the adoption of this law, two specialized administrative bodies responsible for the implementation of government in the sector were established, namely the Committee on the Price of Medicines and the Committee on Transparency. Later, the amendments to the Act also introduced the Positive Medicines List (PML), which is legally defined in §1(47) of the Supplementary Provisions to the Act. The current regulation of the pricing of medicinal products is introduced by the Medicinal Products in Human Medicine Act 2007, which at the legal level provides detailed regulation of the pricing of medicinal products. The amendments that the law undergoes, as well as the regulations under its application, have a significant impact on the PML, which, as the doctoral student points out, becomes the main legal institute on the basis of which the mechanisms and procedures for the price regulation of medicinal products are built.

I consider that the conclusion drawn on page 34 concerning the use of the terms 'Minister' and 'Ministry' in legislative acts, according to which the reference in the relevant legislative act to 'Ministry' means that there is a legal delegation of powers to other bodies under the responsibility of the Minister, is not consistent with the general rules governing the structure and organisation of administrative bodies and their administration in the Administration Act, on the one hand, and with the principles of administrative law governing the delegation of powers, on the other.

Chapter Two explores the concept of "medicinal product", as legally defined in the Medicinal Products in Human Medicine Act, and the author makes his own qualification based on the administrative regime and defines medicinal products as those included in the PML, prescription-only medicinal products not included in the PML and non-prescription products. I recommend extending the study to the part concerning the distinction between the third category of 'non-prescription medicines', which are medicinal products, and food supplements which, by their characteristics, are similar to that group of medicinal products. It is also necessary to examine whether the Medicines Agency has powers over food supplements, in so far as they are subject, in the same way as medicines, to registration and verification of their content and are sold in pharmacies and not in grocery stores, the control of which is monitored by the Bulgarian Food Safety Agency. The designation of the parties to the procedure for the registration of medicinal products and their designation as entities is imprecise in so far as the applicant, who is the potential holder of the marketing authorisation, can participate in the procedure only as a 'party' and not as an entity. The subject of the proceedings is undoubtedly the competent administrative authority empowered to issue the relevant administrative act, which, according to the doctoral student, is the National Council on Prices and Reimbursement of Medicinal Products (p. 51). In this regard, it should be clarified whether it is the NCPRMP that is the specialised administrative body for the registration of medicinal products, in so far as the Medicines Agency has such powers, on the one hand, and on the other hand, to distinguish the powers of the competent authorities regarding the procedures for registration of medicinal products and that for determining their price, or whether it is stated that there is no basis in the law for distinguishing procedures. This is because we are talking about one procedure of 'registration and regulation' and, in my view, we are talking about two separate procedures – the procedure of registration of the medicinal product and the procedure of pricing and reimbursement of medicinal products in human medicine, which is developing, as indicated in the study, between the applicant (the marketing authorisation holder) and the NCPRMP. I recommend, in this connection, examining, from a procedural point of view, whether an administrative procedure is actually taking place between an applicant and an administrative

authority, in particular the NCPRMP, if the answer is in the affirmative, specifying the stages of the procedure itself.

This chapter also deals with the PML, which is defined as a mechanism for regulating the prices of medicinal products paid with public funds. I share the dissertation's opinion on the nature of the PML, whose purpose is to disclose decisions on administrative acts already issued by the competent administrative authority.

The third chapter deals with the issues related to price formation, respectively price caps of the different types of medicinal products. The presentation concerning the formation of price caps for medicinal products subject to medical prescription, which are not included in the PML, and the author's conclusion that the regulatory act contains two completely identical texts concerning the pricing structure of medicinal products included in the PML and those which are not included in the PML but are subject to medical prescription, are of a beneficial nature. It is stated that, in so far as the structure of the price formation in these cases is identical to that of the products included in the PML, the marketing authorisation holders apply to the Council for the formation of a price cap before or in parallel with the application for inclusion of the medicinal product in the PML, since the first procedure is shorter and the medicinal product can be sold on the territory of Bulgaria, on the basis of Article 216b of the Medicinal Products in Human Medicine Act. In this regard, I recommend that the author make a proposal to amend the regulatory framework, which will prevent the occurrence of these contradictions. I cannot agree with the reference to page 77 concerning the determination of a possible refusal to register the price of a medicinal product not subject to medical prescription as 'manifestly unlawful', without examining the specificity of the case in accordance with the authority's powers, the factual circumstances and the application of substantive law, in accordance with the principles of the exercise of administrative powers laid down in the Administrative Procedure Code. It should be noted that, in the administrative procedure, the correctness of the application is checked in the first place and, once any irregularity has been remedied, an admissibility check is carried out, in accordance with the established procedural conditions for admissibility (p. 84). In the event of inadmissibility of an application for an individual administrative act, the administrative authority shall leave the application 'without examination' and shall terminate the proceedings as inadmissible. Again, I recommend that a proposal be made to amend the Regulation in the light of what is stated on pages 84 and 85, and that the statement be extended to other theoretical sources concerning the concept of 'interested parties'.

I find the conclusion on p. 89 that, in so far as the law uses the term 'appeal' against Council decisions and not 'challenge' to be unfounded, this precludes a public prosecutor from lodging an appeal against the decision, even where it is necessary to do so in order to protect

an important State or public interest. It is also appropriate to examine the question of the administrative appeal, indicating whether, where appropriate, it is admissible in so far as it is claimed that the appeal against the Council's decisions is based solely on legality.

Chapter 4 deals with the administrative acts of the NCPRMP in general, without specifying their specific legal nature. Indicate the practical problems associated with the different point in time at which the obligation to comply with them began for the addressees and other authorities and/or stakeholders. The challenge to the Council's administrative decisions and the question raised by the author concerning the 'subsequent act' which will be subject to judicial review, account should be taken of Article 145(2) of the APC, which provides an answer to this question. My opinion is that the challenge before the Transparency Committee, in accordance with the current legislation, is an administrative challenge, and the argument in this regard is the provision of Article 93 of the Code, which determines the higher administrative authorities in cases of administrative challenges to administrative acts, where they are not part of the administrative structure of the authority that issued the act.

In conclusion: The research is consistent with the topic, it shows the author's skills to analyze in detail the legal institutes, part of the subject of the topic, to place accents and to isolate problems, including to make critical remarks, which I recommend to grow into specific proposals *de lege ferenda*.

The content of the dissertation complies with Article 6(3) of the Law on the Development of Academic Staff in the Republic of Bulgaria and Article 27(2) of the Regulation on its implementation.

In view of the above, I propose that the scientific jury should award the educational and scientific degree of Doctor in the Field of higher education 3.6 'Law', doctoral program "Administrative Law and Administrative Procedure" to Vasil Chavdarov Tankov, a doctoral student at the Department of Public Law Studies of the Faculty of Law of Plovdiv University 'Paisii Hilendarski'.

Signature:

/Prof. V. Kanatova-Buchkova, PhD/

22.05.2025