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ADMINISTRATIVE REGULATION OF PRICES OF MEDICINAL PRODUCTS IN BULGARIA

AUTHOR'S ABSTRACT
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CONTENT

INTRODUCTION

It is characteristic of market economies that prices on the market are mainly regulated by the principles of supply and demand, and the state has the function of creating rules for the fair functioning of the particular market and for saving the established rules. With regard to medicinal products in Bulgaria, these market principles are not applicable, and pricing is subject to strict regulation by the state. It is the established administrative regime of regulation of the prices of medicinal products in Bulgaria that is the main subject of this dissertation.

The main purpose of the author of this dissertation is to study in detail the current legal regulation of the pricing of medicinal products, showing the historical trends underlying it and at the same time to make a critical analysis with a view to its future improvement. In order to realize this dissertation and achieve its goal, several main tasks should be fulfilled: First, a detailed legal-historical analysis of the existing legal framework in the past must be carried out. Next, the basic concepts, the subjects of administrative relations and the mechanisms

applied in the specific sphere of government should be clearly defined and established. Once the subject matter, the subjects and the mechanisms in their static are clarified, they are also considered in their dynamics as functioning administrative legal proceedings. At the end, the issues related to the entry into force of individual administrative acts, their appeal and legal liability for non-compliance with the established obligations are discussed.

The practical significance of this dissertation is expressed in the preparation of a systematic and in-depth study of the administrative regime of regulation of the prices of medicinal products. The research will be useful for legal practitioners, students and researchers.

CHAPTER FIRST Historical overview of the development of the regime for regulation and registration of prices of medicinal products in Bulgaria

Part I. Sources of law and their development

§ 1. Provisional Rules for the Structure of Medical Management in Bulgaria (1879)

Prepared by the Bulgarian doctor Dr Dimitar Mollov and approved by Prince Alexander Dondukov-Korsakov on 1 February 1879, the Provisional Rules are divided into three parts, the third part, entitled 'Temporary Rules for the Structure of Pharmacies in Bulgaria', lays down the terms and conditions under which pharmacies are established and managed, the rules for preparing and dispensing medicines. The section entitled 'Pharmacy fee', which contains rules on the formation of drug prices, discounts and surcharges, is of interest for this study. It states, for example, that when a medicine is dispensed for the treatment of livestock, the medicines may be of a lower quality and the price may be reduced by 25% of the amount indicated in the pharmacy charge (§ 45, point 1), respectively, medicines imported may be sold by pharmacies 30% more than they were bought (§ 45, point 3). The provision set out in § 32 is also interesting, according to which: 'If you find that the remedy awarded is paid more than it costs

according to the pharmacy charge, the guilty person is brought to justice, and the more expensive person has the right to seek reimbursement from the guilty person', i.e. both criminal and compensatory liability for such acts is provided for.

§ 2. Sanitary Law (1889)

Drafted during the reign of Prime Minister Stefan Stambolov and promulgated in State Gazette No 11 of 28 January 1889, this Act also became the normative basis for the creation of a relatively sustainable health system based on the ideas of health care characteristic of European countries in the last decades of the 19th century. The following principles of the pricing process can be inferred from this normative text:

- to entrust pricing to a higher administrative body;
- a fixed period for revision of the fixed prices;
- keeping prices in line with European price developments;
- taking into account local conditions when setting final prices;

All these principles, laid down more than 130 years ago, we will find them, actually functioning today, embedded in the system built through the mechanism of the Positive Drug List.

§ 3. Public Health Protection Act (1903)

The law continues the direction of upgrading the regulatory framework and building health care, set by the Sanitary Law.

§ 4. Public Health Act (1929)

This law is considered one of the most perfect, regulating this circle of social relations. With regard to pharmaceutical activities, one can note the creation of a specialized body to participate in the preparation of the pharmacy fee, and this is the Pharmacy Commission. Only one normative text is separate to the regulation of prices and this is the text of Art. 286. However, in addition to all the

principles established and formulated in the previous regulations, qualitatively new elements have been added: the inclusion in the price-setting process of a narrowly specialised body, such as the Pharmacy Commission, a review of the fee, both for a certain period and if necessary, the comprehensiveness of the pharmacy fee has been introduced – the inclusion in its scope of all authorised medicines. The Public Health Act was in force until the early 1950s.

§ 5. Public Health Act (1973)

This law reaffirmed the system built between 1952 and 1953, based on the principles of socialist health care. The medicinal part is covered in Chapter 10 'Pharmacy', but the issue of pricing does not appear at all. In view of the current principles of a planned economy, this is not surprising, since at that time the regime of state price regulation was not an exception for certain socially significant goods, but a universal mechanism. Following the 1989 amendments, an Act amending and supplementing the Public Health Act was adopted in early 1991, putting an end to the state monopoly in the field of trade in medicinal products. This amendment also provides for the establishment of a Pharmacy Council under the Ministry of Health, which is also empowered to 'give an opinion to the public pricing authority on the pricing of medicines and other medical goods'.

§ 6. Medicinal Products and Pharmacies in Human Medicine Act (1995)

With this normative act, the matter concerning medicinal products is completely removed from the health legislation and for the first time receives its own legal regulation at the level of the law. Chapter Nine, entitled 'Prices of medicinal products', is devoted to the prices of medicines and consists of a single legislative text, Article 85. According to him, the regulation of the prices of medicines is the exclusive competence of the state, with the Council of Ministers being the body that determines the maximum amount of profits and overcharges,

and the Ministry of Health registering and promulgating in the State Gazette the drug prices proposed by the manufacturers.

In 2000 and 2002 amendments were made to the Act, which laid the foundations for the establishment of the current institutional and regulatory framework – two specialised administrative bodies such as the Drug Prices Commission and the Transparency Commission – and the Act amending the Health Insurance Act of 2002 introduced the Positive Medicines List Institute.

§ 7. Medicinal Products in Human Medicine Act (2007)

The historical review ends with the current MPHMA, adopted on 30 March 2007 by the XL National Assembly, the law promulgated in State Gazette No 31 of 13 April 2007 and entering into force on the day of its promulgation. The detailed review of the regulation of the pricing regime established by this Act is made in essence in the following chapters of the dissertation, in the relevant systematic places.

Part II. Types of crucial organs over the years. Competence and functions

§ 1. Ministry responsible for health

At the top of the hierarchical pyramid, the minister responsible for healthcare has always been the body with the broadest competence. Initially, this was the Minister of the Interior, and after the amendment to Article 161 of the Tarnovo Constitution of 1911, 'people's health' was explicitly added to the portfolio. On 09.09.1944, by Decree No 14 of the Regents of Bulgaria, on the basis of a Report by the Prime Minister Kimon Georgiev, an independent Ministry of Public Health was established. Subsequently, in the course of the years, the 'social care' portfolio was added to the Ministry on two occasions, changing its name from 1950 to 1968 and again in 1987. On 21 September 1990, by decision of the VII Grand National Assembly, 'social care' was transferred to the newly created Ministry of Employment and Social Welfare, and the former Ministry of Public

Health and Social Welfare was transformed into the Ministry of Health that still exists today.

§ 2. The Medical Council. Supreme / Supreme Medical Council

Legislation from 1879 to 1929 provided for the existence of a body to which both advisory and direct administrative functions were assigned. Such a body, called by the Interim Regulations - the Medical Council, by the Sanitary Act and the Public Health Protection Act - the Supreme Medical Council, by the Public Health Act of 1929 - the Supreme Medical Council, existed alongside the bodies that were functionally part of the structure of the Ministry itself. It was for that authority to draw up and amend the pharmacy charge, which was the administrative act fixing the price of the medicines at that time. The Public Health Protection Act of 1903 established a specialised body, the Pharmacy Commission, with its members taking part in the meetings of the Supreme Medical Council with voting rights when 'pure pharmacy matters' are discussed.

§ 3. Administrative Price Bodies since 1989

The Act amending the Public Health Act of 1991 provides for the establishment of a Pharmacy Council at the Ministry of Health. Although that authority does not itself have the power to set the prices of medicinal products, it is nevertheless given the opportunity to 'give an opinion to the State pricing authority on the pricing of medicines and other medical products.' That first legislative step, following the 1989 changes, began the re-establishment of the system of specialised administrative bodies entrusted with administrative functions in the process of pricing medicinal products. In 2000, two specialized bodies were established to carry out government in the sector. These are the Drug Price Commission of the Ministry of Health and the Transparency Commission of the Council of Ministers. This structure with two bodies - one essentially and one control body - still exists today, but today the NCPRMP is presented with the full competence of a decision-making body, unlike the Commission of 2000, which

was only a subsidiary body to the Minister.

§ 4. General regulatory authorities

Apart from the bodies with direct competence in pricing, the bodies with more general competence in the pharmaceutical sphere, such as the Drugs Executive Agency and the structures that have preceded it historically, are also considered, starting with the Chemical Laboratory at the Directorate for the Protection of Public Health since 1904, which marked the beginning of drug regulation in our country. The National Health Insurance Fund is also considered as a body that is not only entrusted with public funding, but also has a role in the general health policy.

CHAPTER TWO Subject, Subjects and Mechanism in the Registration and Regulation of the Prices of Medicinal Products in Bulgaria

Part I. Medicinal product. Distinguishing from its related phenomena

§ 1. Medicinal products

Medicinal products are chemical substances which have properties for treating, preventing or diagnosing diseases in humans, as well as for correcting their physiological functions, and which achieve their action through a pharmacological, immunological or metabolic pathway.

For the purposes of the dissertation, the following classification has been introduced, based on their administrative legal regime and according to which medicinal products are divided into: (a) medicinal products included in the PDL, (b) medicinal products subject to medical prescription not included in the PDL and (c) medicinal products not subject to medical prescription.

§ 2. Food supplements

The closest to medicinal products, based on their external characteristics, appear dietary supplements. Food supplements are foods intended to supplement

a normal diet and which are concentrated sources of vitamins and minerals or other substances with a nutritional or physiological effect, used alone or in combination, which are placed on the market in dosage forms, such as capsules, tablets, pills, and the like, in powder, liquid ampoules, and similar liquid and or powder forms intended to be taken in pre-dosed small quantities. The administrative body competent for the registration and control of food additives is the Bulgarian Food Safety Agency, and no special regime is provided for their pricing.

§ 3. Veterinary medicinal products

Veterinary medicinal products shall have identical characteristics to medicinal products for human use, with the exception of the intended use of the former for euthanasia of animals. The competent national authority is the Bulgarian Food Safety Agency, while at EU level the authority is the same as for human medicines - the European Medicines Agency (EMA). With regard to VMPs, there is no regulatory procedure for the formation of their prices.

§ 4. Medical devices

A medical device is an instrument, apparatus, appliance, software, material or other device, whether used alone or in combination, including software, intended by the manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper use, which does not achieve its principal intended action in or on the human body by a pharmacological, immunological or metabolic route, but which may be assisted in its action by devices having such an effect, and which is intended by the manufacturer to be administered to humans in order to: (a) diagnosis, prevention, monitoring, treatment or alleviation of disease, (b) diagnosis, monitoring, treatment, alleviation or compensation of trauma or disability, (c) examination, replacement or correction of an anatomical part or physiological process, or (d) control of the process of pregnancy.

The competent national authority for the registration and control of

medical devices is the BDA. Nor is a regulatory procedure for the formation of their prices laid down in respect of those products.

Part II. Entities in the procedure for registration and regulation of prices of medicinal products

§ 1. Marketing Authorisation Holder

The term marketing authorisation holder refers to the person who is administratively bound to a specific medicinal product. The marketing authorisation holder may be a natural or legal person as well as an unincorporated company. According to the systematic interpretation of the provisions of Article 26(1) and Article 73(1) of the MPHMA, the entities that may be holders of the marketing authorisation under the relevant conditions are:

natural persons, but only upon initial issue of the authorisation. They may not transfer the rights from the marketing authorisation of the medicinal product, nor may they be acquirers in the event of such transfer;

legal persons in all cases of initial issue or subsequent transfer;

a grouping which is not a legal person. Such a grouping may be a MAH, but only after the rights under an authorisation already granted have been transferred to it by a previous holder, and that grouping may not subsequently itself transfer the acquired rights.

The administrative link between the marketing authorisation holder and the medicinal product is reflected in the number of legal obligations which the marketing authorisation holder has in relation to its placing on the market and its subsequent monitoring. Last but not least, the marketing authorisation holder is obliged to register the price of the medicinal product and is therefore the entity which, as applicant, initiates the administrative procedure for the initial determination of the price of the medicinal product.

§ 2. National Council on Prices and Reimbursement of Medicinal Products

The competent state authority for the registration of the prices of medicinal products is the National Council on Prices and Reimbursement of Medicinal Products (NCPRMP/Council). It was established by Article 258 MPHMA as a legal entity to the Minister of Health with the status of a state commission.

The Council is considered and characterized as a central, collegiate body, with special and in particular sectoral competence, formed by a superior executive body. The scope of the competences conferred on it is examined and the main functions are grouped under five headings concerning: price regulation, positive drug list, monitoring and evaluation of the effectiveness of drug therapy, control and other functions. It describes its structure, the way of functioning, as well as the explicitly stipulated by the law obligation for the members and employees of the Council for protection of official secrecy.

Its management is carried out by a Secretary General, who manages, coordinates and controls the functioning of the general and specialized administration.

Part III. Positive Drug List

§ 1. General Characteristics of the Positive Drug List

The Positive Drug List (PDL) applied in Bulgaria, as well as a mechanism for regulating the prices of medicinal products paid with public funds, is a specific institute through which, on the basis of the principles set out therein, the regulation of the prices of these medicinal products is achieved. Similar, albeit simpler, price lists of medicines, as evidenced by the historical review in chapter one, were introduced by the Provisional Rules for the Structure of Medical Management in Bulgaria of 1879 and the subsequent laws regulating this matter. In the legislation until 1944, this type of price list was called a pharmacy, and subsequently a pharmacy fee. After democratic changes, it was only in 2002 that a similar list was reintroduced into legislation, which was for the first time called the ‘Positive Medicine List’.

On the legal nature of PDL, there are diametrically opposed views, from its acceptance as a normative source of law to the denial of its normative nature and its definition as a set of individual administrative acts. According to the author, both opinions are erroneous in so far as the PDL neither contains legal rules nor directly gives rise to rights and obligations for individuals, still less is it a kind of almanac of the issued IAA on the pricing of medicinal products. In fact, the Positive Medicines List is a kind of legal and technical mechanism for disclosure and mutual regulation of the prices of medicinal products, where the Council Decisions are only the basis for listing and recording the relevant information. Medicinal products subject to medical prescription, classified by pharmacological groups according to the anatomical-therapeutic-chemical classification code, shall be included in the Positive Drug List.

§ 2. Anatomical Therapeutic Chemical Classification (ATC)

Anatomical-therapeutic-chemical classification is a method of classification of drugs developed by the World Health Organization. According to this system, drugs are divided into groups depending on their therapeutic and chemical characteristics and/or the human organ or system on which they affect. Drugs are classified into groups at five different levels, and the code assigned to them is formed as a series of indicators at each of these levels.

§ 3. International Non-proprietary Name (INN)

International Nonproprietary Name (INN) is the recommended name of the active substance approved and published by the WHO. International non-proprietary names facilitate the identification of pharmaceutical substances or active pharmaceutical ingredients of several substances. Each INN is a unique name that is recognized worldwide and is in the public domain. Public knowledge in the present case means that, unlike a trade mark under which a medicine containing a specific active substance is placed on the market and which a trade mark can be used only by (or with the permission of) the entity holding the rights

to it, there are no, and can be no, legal restrictions on its use in respect of an international non-proprietary name. The non-proprietary name is also known as a generic name. The INN system, as it exists today, was introduced in 1950 by World Health Assembly resolution WHA3.11 and became operational in 1953, when the first list of international non-proprietary names for pharmaceutical substances was published.

§ 4. Structure of the Positive Drug List

The positive list is composed of the medicinal products included in it and is presented in tabular form in the form of four annexes.

- Annex 1 - medicinal products intended for the treatment of diseases, which are paid under the Health Insurance Act. These are the medicinal products that are paid with funds from the budget of the NHIF;

- Annex 2 - medicinal products paid from the budget of medical establishments under Article 5 of the Medical Establishments Act and from the budget of medical establishments with state and/or municipal participation under Articles 9 and 10 of the Medical Establishments Act;

- Annex 3 - medicinal products intended for the treatment of AIDS, infectious diseases, diseases outside the scope of the SCI, as well as vaccines for mandatory immunizations and re-immunizations, vaccines on special indications and in exceptional circumstances, specific sera and immunoglobulins.

- Annex 4 - includes the price caps indicated by its constituent elements, at which the medicinal products included in the first three applications of the PDL may be sold at wholesale and/or retail level (directly in the pharmacy network) when they are not paid for with public funds.

§ 5 Functions of the Positive Drug List

The use of PDL mechanisms aims to achieve wider access to quality treatment for more patients and at the same time to ensure the effectiveness of the funds spent on it. Often, especially for rare diseases, medicines may be of too high

a value, it would be impossible for patients to finance their treatment themselves. In this case, the principle of social solidarity is triggered: the whole of society, by paying its social security contributions and taxes, generates a resource that is used to pay for the treatment, including drug therapy, of those who need it at this time. On the other hand, in so far as this is a disposal of a public resource, society has due care that these funds are spent as efficiently and appropriately as possible. This public spending efficiency function is ensured by two mechanisms to achieve the lowest reference price, external and internal referencing. I.e. the pricing of a product in the PDL, as well as subsequent price changes, should take into account the lowest price per manufacturer of the same medicinal product in certain reference countries (these are Belgium, France, Greece, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia and Spain) – the so-called external reference pricing. In the internal reference pricing, the medicinal product to be included in the PDL is compared with the price of other products already included with also an international non-proprietary name.

CHAPTER THIRD Formation and recording of prices of medicinal products

Part I. Price formation of medicinal products

§ 1. Price formation of a medicinal product included in the PDL

Before proceeding with the procedure of registering the price of a medicinal product, the price itself must first be formed.

The price of medicinal products included in the PDL is formed by the following elements:

- a producer price which may not be higher than the BGN equivalent of the lowest producer price for the same medicinal product in the ten reference countries: Belgium, France, Greece, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia and Spain;

- a wholesaler's margin of 7 % if the declared producer price is up to BGN 10.00, 6 % if the producer price is between BGN 10.01 and BGN 30.00, and 4 % but not more than BGN 10 if the declared producer price is more than BGN 30.00;

- a retailer's margin of 20 % at the declared producer price is up to BGN 10.00, 18 % if the declared price is in the range of BGN 10.01 and BGN 30.00 and 16 % respectively, but not more than BGN 25 if the producer price is above BGN 30.00;

- VAT - the marginal price of a medicinal product is calculated as the sum of the above three elements plus value added tax;

When verifying the ex-works price of a medicinal product, the Council used the prices published by the State institutions as well as information from the EURIPID Collaboration database.

§ 2. Formation of price caps for prescription-only medicinal products not included in the PDL

The structure and criteria for setting a price cap for prescription medicines are exactly the same as those applied to medicines included in the PDL and consist of the same elements: producer price, which may not be higher than the BGN equivalent of the lowest producer price for the same medicinal product in the 10 reference countries, wholesaler margin, retailer margin and value added tax.

§ 3. Price formation of non-prescription medicinal products

As regards the prices of non-prescription medicinal products, the legislature did not lay down any specific mechanism for determining, comparing or attaching them to the values in reference countries or any other specific requirements. There are also no allowances for wholesalers and retailers. The

manufacturer's price is not sought either. The Council should register maximum retail selling prices of non-prescription medicinal products as proposed by the marketing authorisation holders.

Part II. Proceedings for price regulation and registration before the NCPRMP

§ 1. Initiation of production

For the three types of medicinal products - those included in the PDL, those subject to medical prescription that are not included in the PDL and those that are available without medical prescription, the Ordinance provides for a procedure that generally develops in three main steps: application, examination of the application and enactment of the final administrative act.

For the inclusion of a medicinal product in the PDL (which implicitly also includes the setting of its price), for the regulation of a price cap for a medicinal product subject to medical prescription not included in the PDL and for the registration of a price for a medicinal product not subject to medical prescription, the marketing authorisation holder or its authorised representative shall submit an application for the setting of a price cap or registration in accordance with a model approved by the Council. In the case of a medicinal product subject to medical prescription, the application must indicate the price of the items discussed in detail in the previous chapters, but in general these are the producer price and the margins for wholesalers and retailers within the relevant limits, according to the value of the declared producer price.

In general terms, looking at the volume of documents submitted to the administrative authority, the expert assessments carried out in the course of the proceedings and the time limits for examination and adjudication, the three specific proceedings can be ranked in the following order: as requiring at least documents, only one expert assessment and with a shorter (30-day) time limit for adjudication, is the procedure for registering the price of a medicinal product not subject to medical prescription; next, requiring additional documents, a second

expert assessment, but with a ruling within the same 30-day time limit, is the procedure for the formation of a price cap for a medicinal product subject to medical prescription that is not included in the PDL. The most complex and document-intensive and expert work is the price-validation procedure for the third type of medicinal products, those that apply for inclusion in the PDL. The lead time and the assessments that are made in the course of such proceedings depend on the extent to which the applicant and evaluated product is new to the PDL or has a product already included with the same INN. The Council examines the application and decides on the approval of a price and inclusion in the PDL or refuses to approve a price and include in the PDL within 60 days of the application for medicinal products that have applied for inclusion in the PDL and for payment with public funds. With regard to medicinal products belonging to a new international non-proprietary name for which a health technology assessment has been carried out, the Council shall act within 180 days.

§ 2. Eligibility and regularity check

The Ordinance does not explicitly provide that the administrative authority should check the admissibility of the request made to it, but this procedural action should be done under the general rules of the APC. In accordance with the provisions of Article 27(2) of the Code of Administrative Procedure, the administrative authority must verify the conditions for the admissibility of the request. If the request is admissible, the next step is to check the regularity of the submitted application.

In the event that the submitted application does not comply with the established requirements, the Council should request the applicant to remedy the deficiencies and shortcomings in the documentation, as well as if additional information is needed. In that case, the time limit for delivery of the judgment shall be suspended until the date on which the deficiencies and shortcomings in the documentation have been remedied.

§ 3. Notification of initiation of proceedings

The special rules of the MPHMA and the Regulation do not provide for the notification of interested parties of the initiation of proceedings. For this reason, Article 26 of the APC, which requires the administrative authority to notify known interested citizens and organisations, in addition to the applicant, of the initiation of the proceedings, should be directly applied. The purpose of notification is, on the one hand, to enable interested parties to defend their interests and, on the other hand, to make it possible to complete the file with the most complete information on the facts and circumstances relevant to the proper resolution of the file. In practice, however, the Council does not make such a notification, so that third parties will be able to become aware of the administrative procedure which has already been concluded only after the decision has been entered in the relevant public register.

§ 4. Preparatory actions and substantive examination

For each application for registration of the price of a medicinal product not subject to medical prescription, only a legal assessment shall be made. Applications for the setting of a price cap for a medicinal product subject to medical prescription that is not included in the PDL shall be subject to a legal and economic assessment, and applications for the inclusion of a medicinal product in the PDL shall be subject to a legal, medical, pharmaco-economic and economic assessment. Appropriate evaluations shall be carried out by experts from the specialised administration of the Council. The experts shall carry out a preliminary examination of the applications and the accompanying documentation and draw up an opinion on each application in accordance with a model approved by the Council.

Within thirty days of the date of submission of the application, the Council shall examine the application and the documents attached thereto and take a decision approving or refusing to approve a price cap for prescription-only medicinal products not included in the PDL, and shall decide on the registration

of a price for the non-prescription medicinal product. For medicines for which inclusion in the PDL is requested, the period for consideration of the application shall be 60 days from the date of submission of the application, and where the application is for inclusion in the PDL of a medicinal product with a new international non-proprietary name subject to health technology assessment, the period shall be 180 days.

§ 5. Change and deletion of approved/registered price

Once registered, the value of the medicinal product does not remain fixed and unalterable over time. However, there are special rules and procedures for making the relevant changes, similar to those for the initial registration.

When the change in the price of medicinal products subject to medical prescription is registered, a number of special conditions are laid down where the change is limited to a request for an increase in the price. The first condition is that an increase may not be applied for earlier than 12 months after the last price has been confirmed, and the second condition concerns the amount of the increase requested – it must comply with two criteria: the amount of the lowest price for the same medicinal product established in one of the reference countries or, in the absence thereof, the rate of statistically recorded inflation during the period of validity of the last price formed. Logically, in the event of a price reduction, no regulatory restrictions are provided for. Restrictions are not provided for all forms of variation in the price of non-prescription medicinal products.

The registered price of a medicinal product may be cancelled either on the initiative of the marketing authorisation holder or ex officio by the Council. Where, upon application by the MAH, a medicinal product is excluded from the Positive Drug List and its price is removed from all PDL applications, the marketing authorisation holder may request that its current price be entered as a price cap in the register of price caps for medicinal products subject to medical prescription. The ex officio deletion of the price occurs in cases of suspension, withdrawal or expiry, without renewal, of the marketing authorisation for the

medicinal product. In this case, the Executive Agency for Medicines shall notify the Council electronically within three days of the expiry of the marketing authorisation or of the entry into force of the act withdrawing or terminating it.

§ 6. Declaration in the absence of a change in the price of medicinal products included in the PDL

In the case of medicinal products included in a PDL, even the absence of a change in their price is a condition for certain legal consequences. In the event that no change in price has been requested, every six (in the case of a single INN medicinal product) or twenty-four months (in the case of other products in the relevant group) since the date of validation of the last price, the marketing authorisation holder shall submit a declaration in a form approved by the Council certifying that there has been no change in the ex-works price on the basis of which the last price was validated. The procedure laid down in Article 43 of the Regulation, in addition to the obligation for the MAH to declare, necessarily provides for an ex officio check by the Council. In case this check reveals a lower price that has not been declared by the MAH, the Council gives the opportunity to request the corresponding price change. In case of inaction by the MAH, the Council, again ex officio, has the right to change the price in accordance with the values established by the MAH.

§ 7. European legislation and practices on the regulation of the pharmaceutical market in Europe and the United States

First of all, it should be noted that, in practice, there is no single market for health services and, in particular, for medicinal products that purchase health systems in the Member States of the European Union. As price regulations at national level and the needs of individual Member States are very different, *de facto* markets are also strictly national. Different Member States have put in place different measures to control and administer pricing processes, take reimbursement decisions and negotiate with public funds, so as to ensure the

efficient use of public resources.

Unlike European countries, the U.S. does not have a centralized system to control drug prices. The functioning of the current mechanism combines the dynamics of the free market with various legislative initiatives. The lack of a single centralised system compensates for a multitude of different authorities and market actors (insurers and insurance funds) to regulate different aspects of the pharmaceutical industry and pricing.

CHAPTER FOUR Legal nature of acts on registration of prices of medicinal products. Entry into force and contestation. Administrative and criminal liability for non-compliance

Part I. Legal nature of price-registration acts for medicinal products

§ 1. General characteristics of individual administrative acts issued by the Council

Individual administrative acts are the main means by which the state, in the person of the executive authorities, performs one of its most characteristic functions, namely the implementation of executive-ordering activities in connection with the management of processes occurring in the public, social and economic spheres, which are within the scope of government. The National Council for Prices and Reimbursement of Medicinal Products exercises the powers conferred on it by law by 'ruling by reasoned decisions' in accordance with Article 259(4) of the Medicinal Products in Human Medicine Act. The Council's decisions reveal all the typical characteristics inherent in individual administrative acts as defined in Article 21(1) of the Code of Administrative Procedure. In this sense, individual administrative acts of the Council are the decisions by which the authority decides by approving and registering, amending or deleting the price of a medicinal product, or by issuing an explicit (or implicit) refusal.

Council decisions are classified as constitutive, circumscribed acts of a collective body. They are formal, their form is written and contains normatively

defined requisites. In view of the initiative to issue them, the acts can be as an initiative of the addressee, but also, in certain situations and issued ex officio, and according to the effect they have on the addressee of the act as a whole can be considered to be beneficial, in so far as the acts registering a price for the MAH create the right to realize his main economic interest, but namely to market his product.

§ 2. Communication and implementation of the individual administrative acts of the NCPRMP

Decisions of the Council shall, as a general rule, take effect if no appeal has been lodged within the prescribed 14-day period or if they have been confirmed by the appeal body. Since then, the decision has become an obligatory part of the legal peace and should be applied in the relations between stakeholders, which in practice are a very wide range of entities - MAH, Council, NHIF, BDA, medical institutions, wholesalers and retailers of medicinal products, etc.

In general, the Council Decisions will be implemented by the Marketing Authorisation Holder from the day following their entry into force. It is not the same time when actual compliance with the decisions will have to be sought from third parties, such as the Ministry of Health, the NHIF, wholesalers and retailers of medicinal products and medical care providers, who were initially notified only of the acts issued by the Council, but not whether they were appealed, and from what point in time they will be considered stable and enforceable. That time for the third parties listed is significantly later, namely on the 2nd day of the month following the entry into force of the relevant decisions, when the Council announces them in the registers and PDLs it maintains. The introduction and use of a public, compatible and shared common database between the NCPRMP, the NHIF, the MH and the BDA would greatly facilitate communication and their interconnected functionalities, which would not only be in the interest of the marketing authorisation holders and the entities involved in the medicinal market, but also of society as a whole, insofar as this whole organization is created in order

to optimize public spending.

§ 3. Prerequisites for preliminary implementation

Before the expiry of the time-limit for instituting proceedings, acts of the Council may be made enforceable and must be implemented by the addressee and the parties concerned if the need so requires and if the Council has authorised provisional implementation of the act by reasoned order. The Ordinance provides that the Council shall notify ex officio to the Ministry of Health and the NHIF of the decisions to which preliminary execution has been given within 3 days of their issuance.

§ 4. Consequences of the provisional implementation of the acts of the NHIF Board in the case of Articles 5 and 10f(3) of Regulation No 10

The NHIF pays for new medicinal products (new INNs) included in the PDL after receiving a written application from the marketing authorisation holder requesting that the respective medicinal product be paid with public funds generated by the Fund. Applications shall be submitted by 30 December and the payment shall start from the 1st day of the month following the end of the calendar year in which the product concerned is included in the PDL. According to the rules of Ordinance 10, applications must be accompanied by a copy of an effective decision of the Council for the medicinal product concerned. An important element of the prerequisites for payment in the year following the year of inclusion in the PDL is precisely the Council Decision that entered into force by 30 December. In this sense, the issuing of decisions to include medicinal products in the PDL at the end of the year and for which the Council has issued an order for provisional enforcement, but for which the time limit for appeal will expire in the year in which they have already to be paid, do not formally comply with the regulatory requirements for their payment to begin. The provisional enforcement order will give grounds for recording, i.e. including the medicinal product in the PDL, but not for its payment. It is not disputed that there is a general interest in

ensuring access to treatment through faster entry into the reimbursement system for applicant medicinal products, but such access should not be contrary to the legal rules in force.

Part II. Appeal against the acts on registration and regulation of the prices of medicinal products

§ 1. Judicial review of Council decisions

Following the amendments made to Article 266 of the MPHMA (SG No 67/2020), the appeal procedure against Council decisions is fully subject to the rules laid down in the APC and does not contain any specificities or features. The topic of challenging individual administrative acts has been exhaustively examined in legal literature and is therefore not of scientific interest to the present work.

§ 2. Administrative appeal against Council decisions

2.1. Special jurisdictions according to the current constitutional model

The dissertation, based on historical and comparative legal analysis, argues for the admissibility of special jurisdictions according to the current constitutional model established by the Constitution of the Republic of Bulgaria of 1991. It sets out the reasons why the opinions according to which the current constitutional model explicitly prohibits and does not allow the existence of special jurisdictions are too extreme. It is argued that the statement in Article 119(1) of the Constitution of the Republic of Bulgaria that the administration of justice is carried out by courts should not be interpreted restrictively, in the sense that these are the only authorities that have the exclusive right to administer justice. In so far as the separation of powers does not function in its absoluteness, and each of the powers for reasons of economy and convenience of government, or other important considerations of state, in addition to the priority exercise of its functions, may, to a lesser extent, perform functions which fall within the

prerogatives of one of the other powers, without prejudice to the general principle of separation and without transferring the affiliation of the authority concerned to one of the other powers beyond that in which it was created to exist. In this sense, in line with the current constitutional model, an administrative body can be assigned, by way of exception and with explicit legal empowerment, judicial functions, without changing its essential characteristics, and without transforming the administrative body into a court of the category referred to in Article 119 of the Constitution.

2.2. Concept of special jurisdiction within the administration

Jurisdiction means the administration of justice. The special court within the administration is an administrative body entrusted with the administration of justice. These are bodies which perform judicial functions without being organisationally part of the judicial system and which belong to the executive branch of power.

2.3. Characteristics of special jurisdictions

The characteristics of the special courts are determined by determining the organisational position they occupy within the structure of the public authorities and by defining the functional characteristics of the activity entrusted to them, in this case the administration of justice. The signs that define the activity of an administrative body as a judicial and not as a manifestation of the so-called active administration are the following:

(a) resolving a legal dispute – the main function of the court is to resolve a legal dispute on the basis of events that have already taken place and have taken place in objective reality.

(b) referral – the court does not initiate the process of resolving a legal dispute ex officio, but only after due referral by the persons entitled to do so;

(c) adversarial proceedings – these must guarantee the parties the opportunity to make their claims known, to submit the relevant evidence and to set out their objections to the claims of the other party;

d) independence of decision - the person or persons forming part of the judicial body, when it is a collegiate body, in making their decision should be guided solely by their internal conviction, based on the evidence gathered in the proceedings; and

e) possibility of judicial review – the judicial decision issued by the court must be subject to the possibility of judicial review, so that it is the court that has the final say in the legal dispute.

The special courts are thus regarded as administrative authorities which, after having been duly seised and in the context of a simplified adversarial procedure, resolve a dispute with guaranteed independence and autonomy in adjudicating, and the judicial decision issued is subject to subsequent judicial review.

2.4. Comparison of the proceedings before a special court and the contestation of acts of an administrative authority before a higher authority

Two main criteria are considered when distinguishing between proceedings before a special court and those before a higher authority. Firstly, it is the structural and functional link between the authority before which the challenge is made and the authority which adopted the contested act. In one case, it is a directly superior authority within the hierarchical structure of the department concerned and there are corresponding subordinational links between it and the authority which issued the contested act. The special courts, while generally also forming part of the administrative apparatus of the State on a strictly organisational basis, are not part of the internal body of the authority whose acts are challenged before it, or even of that body, but do not have the status of a directly superior body. The next characteristic criterion that distinguishes an administrative appeal from a judicial appeal is the scope of that appeal. Both the lawfulness and the expediency of the administrative act can be challenged in the appeal before the directly superior authority, whereas for the appeal before a court, be it a court or a special court, only the lawfulness of the act issued is subject to

challenge.

2.5. Status and activity of the Transparency Committee of the Council of Ministers

The Council of Ministers establishes a specialised body, the Transparency Committee. The Commission shall be the authority before which an administrative appeal may be brought against decisions of the Council. The dissertation provides an argumentation as to why, in the context of an appeal, the expression 'administrative procedure' should be understood in a broad sense, as a procedure before an administrative authority, even where that authority will rule by a judicial act, and not in the strict sense as synonymous with a challenge before a directly superior administrative authority.

2.6. Are there indications of the administration of justice in the activity of the Transparency Commission?

On the basis of the examined characteristics of the special jurisdictions, an analysis is made of the activity of the Transparency Committee. The analysis shows that the Commission resolves legal disputes, acts only on referral, develops a simplified adversarial procedure, acts independently in resolving legal disputes and acts issued by it are subject to judicial review.

Part III. Legal liability for non-implementation of Council decisions

§ 1. Administrative criminal liability

The text of Article 289 of the Medicinal Products in Human Medicine Act (MPHMA) is examined, the four paragraphs of which also lay down four separate administrative infringements relating to prices, the process of regulation and their application. The first chamber penalises the sale of medicinal products without a registered price or at a price different from that formed. The second is worded in a blanket manner and refers to the breach of one of the obligations laid down in the Regulation. The third and fourth hypotheses concern wholesalers who

sell to a medical institution, respectively to medical institutions, who buy medicinal products included in the PDL at a higher price than the price formed pursuant to the Regulation.

§ 2. Criminal liability

The criminal law rule set out in the test of Article 225(1) of the Penalty Code, which provides for criminal liability for a person who sells goods at a price above the specified or before it is determined or approved in accordance with the established procedure, is examined. Outside of the discussion of the extent to which such a crime has a reason to exist in a market economy, account should be taken of the fact that, even under market economy conditions, there are certain categories of goods whose prices are subject to state regulation, as is clearly the case with medicinal products.

CONCLUSION

In summary, the contribution of this dissertation can be defined in several directions.

On the one hand, this is the legal-historical analysis of the regulatory framework in the field of health care in the period from 1878 to 1944, in so far as for the period under consideration the scientific literature lacks both a systematization of the normative acts, as well as a thorough and detailed analysis of the legal framework, its development, and the trends followed in this regard. Similarly, the argumentation of the admissibility of the special courts as bodies of the administration entrusted with the task of adjudicating according to the constitutional model in force may also be cited as a scientific contribution. The adoption in practice of such a thesis will only lead to an improvement of the system for checking the legality of individual administrative acts, guaranteeing legal entities a faster and specialized administration of justice. Last but not least, the systematization and analysis of the matter related to

the administrative regime of the pricing of medicinal products, which is the essence of the dissertation, is also a contribution.

Next are the proposals *de lege ferenda:*

- amending Articles 26(1) and 73(1) of the MPHMA as regards the types of entities that may be MAHs;

- revision of the texts of the MPHMA and the Regulation, which use the expression ‘the marketing authorisation holder or his authorised representative’;

- a comprehensive version of the Regulation with regard to its structure - the proposal is to lay down the general rules "before a bracket" and to develop in detail only the special ones;

- wording of the terms used in the Regulation ‘The Council shall have the right to request’ and ‘The Council may request’, respectively, in relation to identified shortcomings in the documentation submitted by the MAH in the various proceedings, as well as in the texts of Articles 19 and 41, clearly distinguishing the types of price changes - reduction or increase;

- regulation of the form and details of the decision to include a medicinal product in the PDL and approval of its price;

As well as the proposals of a normative and organizational nature:

- the declaration procedure in the absence of any change laid down in Article 43 of the Regulation is to be carried out entirely ex officio by the Council, and

- the establishment of a public register of proceedings brought before the Council, as well as of acts terminating those proceedings by marking their status in real time – with provisional enforcement granted, appealed, entered into force, etc.;