

TEN YEARS NATIONAL COUNCIL ON PRICES AND REIMBURSEMENT OF MEDICINAL PRODUCTS. STRUCTURE, MAIN OBJECTIVES, METHODOLOGY AND ACHIEVEMENTS

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Abstract

This article provides an overview of the main objectives, tasks, and achievements of the National Council on Prices and Reimbursement of Medicinal Products (NCPRMP). The Council is recognized as a national organization responsible for pricing and reimbursement of medicinal products, aligning with European directives and recommendations while adhering to Bulgarian legislation. The Council is committed to ensuring equitable access to medicines and enhancing the regulatory framework in the healthcare system. Its objectives encompass sustainable regulation, fostering a societal attitude towards health, and promoting transparency in pricing and reimbursement. Notably, the NCPRMP has successfully implemented advanced electronic technologies, leading to improved access to medicines and enhanced transparency. With a focus on continuous improvement and quality management, the Council employs various strategies such as the Common Assessment Framework (CAF) and System-to-System interoperability. Health Technology Assessments (HTA) and monitoring of drug therapy serve as essential tools for improving medicine access and optimizing the allocation of public resources. The monitoring of data on the effect of new medicinal products demonstrates the Council's commitment to staying at the forefront of European standards. Additionally, the Council has been honored with multiple European awards, highlighting its exceptional performance and contributions in the field. The NCPRMP's achievements over the past decade can be attributed to effective collaboration with stakeholders including the Ministry of Health, regulatory authorities, NHIF, and BDA.

Keywords: NCPRMP – structure and objectives, ceiling price, reimbursement rules, E-gov, European activities.

Structure

The National Council on Prices and Reimbursement of Medicinal Products was established in April 2013, and this year marks its 10th anniversary. Currently, the National Council is comprised of various professionals including a physician-pharmacologist as the Chair, two economists, two lawyers, and two master pharmacists.

As per the constitutional bylaws, the NCPRMP has a staff of 44 individuals responsible for its administration, including seven governing body members, one Secretary General, and three directorates with 36 staff members. In accordance with European regulations, leading clinicians in pharmacology, specialized in the relevant clinical area for the evaluation of new health technologies, work closely with the Council.

It is of utmost importance that the activities of the NCPRMP are closely coordinated and interact with the main regulatory bodies responsible for implementing the country's

pharmaceutical policy, as well as with the National Health Insurance Fund (NHIF), the Bulgarian Drug Agency (BDA), the Ministry of Health (MoH), and others. Close cooperation between these institutions is crucial for successfully addressing issues related to ensuring sufficient access to medicinal products and modern technologies. One pressing matter at the state level is the urgent need for modern digitization, enabling full interoperability among the main structures involved in the Council's overall activities, as well as providing affordable medicines for the country's budget and patients.

MAIN OBJECTIVES AND FUNCTIONS

The activities undertaken by the NCPRMP are aligned with the shared values of the public sector, emphasizing legality, professionalism, ethics, social responsibility, corruption prevention, anti-discrimination, equity, citizen/consumer focus, and community orientation.

The stated objectives and defined statutory functions establish the National Council as a significant government entity within the health sector.

In recent years, the public sector has witnessed a transformative shift, demanding adaptability and a swift and appropriate response to heightened societal and business expectations. This calls for the rapid implementation of digital advancements, with a primary focus on enhancing people's health and well-being.

In accordance with the functions outlined in Article 259 of the Medicinal Products in Human Medicine Act, the National Council is responsible for:

- Approving and registering the prices of medicinal products, including the changes and exclusion of medicinal products from the Positive Drug List (PDL).
- Maintaining the reimbursement status of medicinal products listed in the PDL through a review process conducted every three years.
- Endorsement, revocation or modification pharmacotherapeutic guidelines.
- Conducting health technology assessments of medicinal products.
- Determining the medicinal products that require monitoring of the therapy, specifying the time period and the medical establishments responsible for the monitoring.
- Generating national identification numbers for medicinal products.
- Engaging in information dissemination, publishing, and research activities pertaining to pricing, reimbursement, and medicines policy.

The National Council also maintains and updates the following public registers:

- The Public Registers of the Positive Drug List, containing information on the included medicinal products.
- The Public Register of prices for medicinal products included in the PDL and funded by public funds.
- The Public Register of approved ceiling prices for prescription medicinal products not included in the PDL.
- The Public Register of maximum selling prices for over-the-counter (OTC) medicinal products.
- The Public Register of national identification numbers assigned to medicinal products.

LEGISLATION DEFINING THE RULES ON PRICING AND REIMBURSEMENT OF MEDICINAL PRODUCTS IN BULGARIA.

European legislation

In European practice, it is common to establish lists of medicinal products that are covered by the Health insurance system and to regulate their prices through a defined procedure. The Council Directive 89/105/EEC, which focuses on the transparency of measures regulating the prices of medicinal products and their inclusion in National health insurance systems, serves as a framework within the European Union.

Directive 89/105/EEC provides the legal framework without addressing in detail the specifics of pricing for medicinal products. According to Article 168 of the Treaty on the Functioning of the European Union, Member States hold the responsibility for organizing their health systems, providing health services and medical care, and allocating the resources assigned to them. Consequently, the internal laws of the Member States govern the specific measures for regulating prices and determining the conditions for public financing.

In January 2022, Regulation 2021/2282 on Health Technology Assessment (HTA) came into force, aiming to harmonize the activities of Member States in conducting clinical assessments of innovative health technologies. This regulation not only seeks to ensure a high level of patient health protection but also establishes a framework to facilitate cooperation between Member States and the necessary measures for the clinical evaluation of health technologies.

The implementation of the HTA Regulation will follow a phased approach. Joint clinical evaluations for oncology and advanced therapy medicinal products are set to commence in 2025, while all other groups of medicinal products should be covered by 2030.

Despite the harmonized activities, the pharmacoeconomic evaluation as part of the overall Health Technology Assessment remains within the exclusive jurisdiction of each nation.

Bulgarian legislation

The regulatory framework regarding the pricing and reimbursement of medicinal products in Bulgaria is outlined in Chapter Twelve of the Medicinal Products in Human Medicine Act and the Ordinance on the Terms, Rules, and Procedure for Regulation and Registration of Prices for Medicinal Products. This ordinance was adopted under PMS No. 97 on 19 April 2013 and promulgated by SG No. 40 on 30 April 2013.

In order for a medicinal product to be sold within the country, it must obtain marketing authorization from either the Bulgarian Drug Agency (BDA) or the European Medicines Agency (EMA). Additionally, a decision from the National Council on Prices and Reimbursement of Medicinal Products approving the price must come into effect.

The National Council applies various mechanisms in the pricing process as stipulated by national legislation, including:

- External reference pricing: Comparing manufacturer prices with those in ten European countries (Belgium, France, Greece, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia, and Spain) and adopting the lowest manufacturer price.
- Internal reference pricing: Determining the lowest reference value in the respective group at the ATC 5 and ATC 4 levels.
- Inclusion of generic and biosimilar medicinal products.
- Price revision every six months or every 24 months.

One of the conditions for a new medicinal product to be included in the Positive Drug List (PDL) is the existence of a discount agreement between the public payer (NHIF/MH) and the Marketing Authorization Holder.

Medicinal products listed in the PDL and reimbursed by the National Health Insurance Fund (NHIF) undergo subsequent annual negotiations for discounts. They are also subject to inclusion in a mechanism aimed at ensuring predictability and sustainability of the NHIF budget.

REGULATING THE PRICES OF MEDICINAL PRODUCTS

The pricing of medicinal products undergoes rigorous legislative control due to the significant reliance on public funds in the pharmaceutical market. This regulation is an integral part of national medicines policies that aim to enhance treatment accessibility and optimize costs. European countries allocate considerable public spending on medicines, employing diverse measures to contain and decrease expenses. These measures include drug price regulation, external and internal reference pricing, and the establishment of Positive Drug Lists. However, it is crucial to ensure that decisions regarding the allocation of public resources for medicines are based on cost-effectiveness criteria. Cost-sharing schemes also play a role in containing public spending while maintaining access to innovative treatments.

When it comes to medicinal products requiring a prescription, the Council approves their prices, irrespective of whether they are funded by public sources. The approved price in Bulgarian levs consists of several elements:

- the manufacturer's price, which must not exceed the lowest manufacturer's price among the ten EU reference Member States - Belgium, France, Greece, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia and Spain;
- a wholesaler's mark-up of 7%, 6% or 4%, depending on the manufacturer's price, but not more than BGN 10;
- a retailer's mark-up of 20%, 18% or 16%, depending on the producer price, but not more than BGN 25;
- 20% Value Added Tax.

The Council, in collaboration with the Ministry of Health and the National Health Insurance Fund, has the authority to determine whether a medicinal product should be covered by public funds. They operate within their defined competencies to make these decisions.

On the second day of every month, the Council is responsible for the upkeep and revision of the PDL Annexes.

The Positive Drug List (PDL) consists of four Annexes that categorize different medicinal products. Three of the Annexes classify the products based on the reimbursing institution, while Annex 4 provides the prices for the medicinal products included in Annexes 1, 2, and 3.

Annex 1 of the PDL covers medicinal products intended for ambulatory treatment of diseases and is funded by the NHIF budget under the Health Insurance Act. The reimbursement levels for these products range from 50% to 100% depending on the specific condition:

- Medicinal products for chronic diseases that severely impair quality of life or lead to disability and require long-term treatment are reimbursed at 100%.
- Medicinal products for chronic diseases with a high prevalence are reimbursed at 75%.
- All other medicinal products fall under the reimbursement level of up to 50%.

Annex 2 includes medicinal products that are funded by medical establishments with state and/or municipal participation. The reimbursement level for these products is 100% for diseases specified in the summary of product characteristics and marketing authorization. For medicinal products used in the treatment of oncological diseases and paid by the NHIF outside the cost of the clinical pathway, the Annex lists the therapeutic indications and their corresponding ICD codes.

Annex 3 encompasses medicinal products intended for the treatment of AIDS, infectious diseases, diseases not covered by the Health Insurance Act, as well as vaccines for compulsory immunizations and re-immunizations, vaccines for special indications, specific sera, and immunoglobulins. The reimbursement level for products in this Annex is 100%, and they are funded by the Ministry of Health budget.

The Council approves the ceiling prices of prescription medicinal products

Medicinal products requiring a prescription but not listed in the Positive Drug List (PDL) have their prices published in the Ceiling Price Register. The pricing of these products is determined by considering the lowest manufacturer's price among the reference countries when establishing the ceiling price (i.e., the retail price). It is important to note that any increase in the price of a prescription medicinal product cannot occur within a period of 12 months from the last price determination.

The Council registers prices of medicinal products sold without medical prescription

The maximum selling price of an over-the-counter (OTC) medicinal product in Bulgarian lev (BGN) is determined and declared by the Marketing Authorisation Holder, and subsequently registered by the Council. It is important to note that the price of OTC products should not be compared to prices in other reference countries. The prices of these specific medicinal products are made publicly available through the Register of maximum selling prices. Any increase in the registered price of an OTC medicinal product is strictly limited to the rate of statistically recorded inflation during the validity period since the last registered price.

The Council controls the prices of medicinal products in accordance with the prices in the reference Member States

One of the methods employed to lower prices for medicinal products funded by public resources involves the Council's specialized administration verifying whether price changes have occurred in the reference countries. This assessment is conducted periodically, with the frequency determined by the last confirmation date, and encompasses all medicinal products listed in Annexes 1, 2, and 3 of the Positive Drug List (PDL). The verification timeframe varies, either six or twenty-four months, depending on whether the medicinal product is alone in its international nonproprietary name or not. This mechanism serves as the foundation for reducing the financial burden on public resources borne by the paying institution (NHIF or Ministry of Health). Conversely, reducing the prices of medicines that do not carry the reference value results in decreased co-payment amounts for patients, thereby enhancing their access to outpatient treatment.

External reference pricing

By implementing external reference pricing and establishing regulations for pricing, a notable outcome has been the reduction in prices for a significant number of medicinal products. Specifically, in 2022, across countries such as Belgium, France, Greece, Italy, Latvia, Lithuania, Romania, Slovakia, Slovenia, and Spain, a total of 535 medicinal products

experienced decreased prices. Notably, Slovakia witnessed the most substantial impact, with 226 medicinal products offering lower prices compared to their counterparts (Fig. 1).

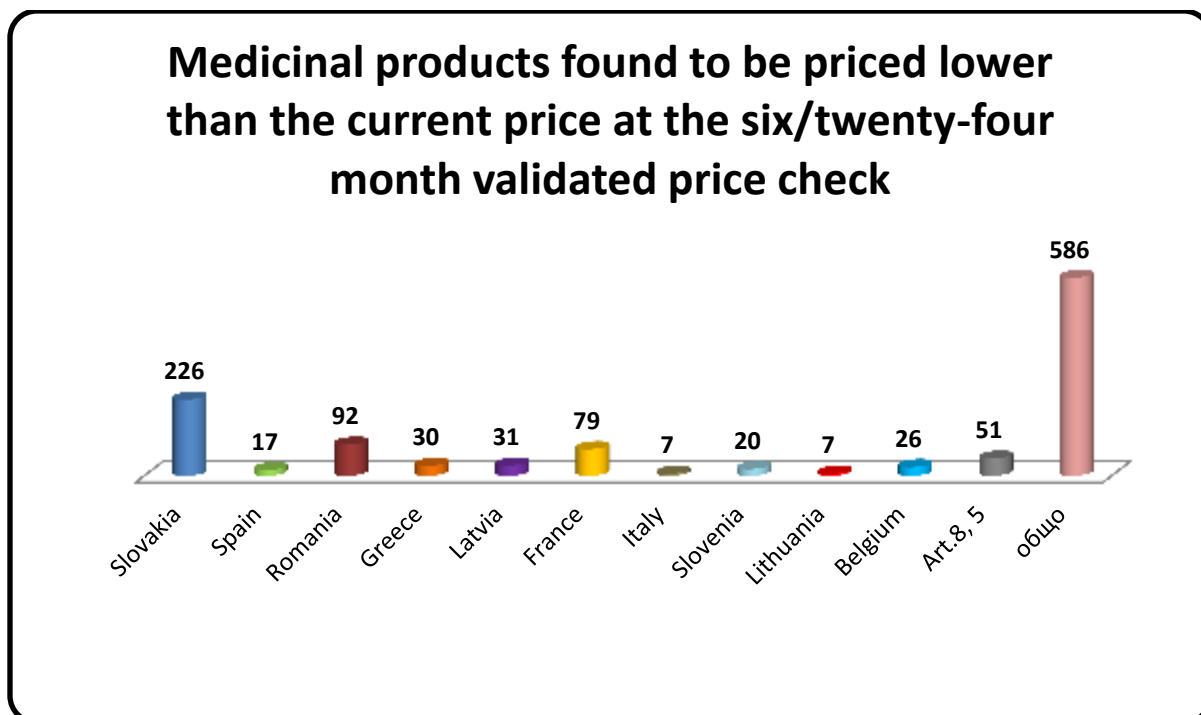


Fig. 1 Medicinal products found to be priced lower than the current price at the six/ twenty-four month validated price check

Internal price referencing

The price regulation of prescription medicinal products included in the Positive Drug List (PDL) incorporates both external and internal reference pricing. Internal reference pricing operates within the PDL and classifies the products based on pharmacological groups using the anatomical-therapeutic-chemical classification code. Within each group, a reference value is assigned for a defined daily dose/therapeutic course, determined by the lowest wholesale or retail price, depending on the reimbursement percentage. For products with 100% reimbursement, the reference value is based on the lowest wholesale price. The reference value coincides with the retail or wholesale price for the reference product, while for other products in the same group listed in Annex 1 of the PDL, the patient is responsible for covering the price difference.

Public spending on medicines included in the PDL and paid by the NHIF/MH is influenced by a variety of factors. One of the main factors is the variation of the reference value for the DDD/therapeutic course of medicines as a result of:

- inclusion/exclusion of medicinal products in the PDL;
- changes in the prices of medicinal products.

The reduction in cost to the NHIF/MH resulting from a decrease in the reference value for the defined daily dose/therapeutic course is driven by several reasons:

- Decreased costs of specific products due to external reference pricing.

- Inclusion of generic and biosimilar medicines, which have manufacturer's prices capped at 70/80% of the price of the corresponding originator/biologic medicine listed in the PDL.

As per the legal framework, the regulations allow for price adjustments of medicinal products listed in the Positive Drug List (PDL) to occur after a minimum of 12 months from the last approved price. These adjustments are either based on the lowest price observed in reference countries or, in cases where no such price exists, by considering the recorded inflation rate over the period since the last price was established.

The factors contributing to the rise in public expenditure due to an increase in the reference value are as follows:

- A surge in the price of a medicinal product associated with the reference value, stemming from a higher price observed in the reference countries. The increment in the reference price is permitted up to the level of the lowest price found among the reference countries.
- A rise in the price of a medicinal product linked to the reference value, adjusted by a certain percentage based on the recorded inflation during the period since the last validated price, in the absence of a price in the reference countries.
- The exclusion of a medicinal product identified by its international non-proprietary name (INN) and associated with the reference value from the Positive Drug List (PDL).

HEALTH TECHNOLOGY ASSESMENT

As the national authority for Health Technology Assessment, the Council has been conducting comprehensive evaluations since January 1, 2019. These assessments include the clinical examination of efficacy, therapeutic effectiveness, safety, pharmacoeconomic parameters, and budget impact analysis for medicinal products with new International non-proprietary names (INN) and new therapeutic indications. Through these Health Technology Assessments, Bulgarian patients gain access to innovative treatments that prioritize safety, maximize health outcomes, and optimize the use of public funds.

A systematic analysis based on the fields of application of newly introduced International non-proprietary names in the PDL is conducted alongside Health Technology Assessments. This analysis incorporates the inclusion of new therapeutic indications, resulting in the expansion of treatment options in various medical areas such as oncology and oncohaematology, dermatology, ophthalmology, rheumatology, hematology, neurology, endocrinology and metabolic diseases, antimicrobials, cardiology, pneumology, psychiatry, gastroenterology, nephrology, obstetrics and gynecology, allergy, and nuclear medicine. These new medicinal products aim to provide additional therapeutic benefits or address unmet medical needs.

In 2021, Regulation 2021/2282 on Health Technology Assessment was adopted to ensure a high level of health protection for patients and users of health technologies. To implement this regulation effectively at the national level in 2023, the Council representatives actively participated in initial meetings held in Lisbon and Stockholm. The Council has appointed its representatives to various sub-groups under the Coordination Group, which include specialists from the Ministry of Health, the National Health Insurance Fund, and the Bulgarian Drug Agency. The objective is to develop sustainable expertise across all relevant state institutions involved in medicines policy. The sub-groups in which Bulgaria has designated representatives are:

- The subgroup responsible for developing methodological and procedural guidance.
- The subgroup focused on joint scientific consultations.
- The subgroup responsible for identifying emerging health technologies.
- The subgroup dedicated to joint clinical assessment.

In 2024, several actions are planned, primarily involving amendments and supplements to national legislation, the adoption of methodological and procedural guidelines, structural changes, capacity-building through training programs for national authorities, and the training of experts.

The adoption of Regulation 2021/2282 on Health Technology Assessment has presented new and significant challenges for the National Council, particularly in terms of building expert capacity, staffing, and adapting the activities of the Authority. Member States with extensive experience in Health Technology Assessment also face similar challenges. Consequently, the restructuring and sustainable capacity-building required to safeguard national budgets and the interests of Member States were extensively discussed during the meeting of agencies responsible for Health Technology Assessment in Lisbon. Bulgaria has been actively involved in all relevant formats and meetings at the European level, effectively addressing these challenges.

MONITORING THE EFFECT OF DRUG THERAPY

Implementation of a specialized module for monitoring the therapeutic effects of medicinal products has been initiated.

The primary objective of this monitoring module is to evaluate the efficacy of drugs in real-world scenarios, comparing them with data obtained from clinical trials and information on alternative treatments funded by public resources.

Specific conditions and criteria for monitoring the therapeutic effects of medicinal products are established, along with an estimation of the number of patients to be monitored during the initial reimbursement phase. Medical establishments responsible for conducting the therapy monitoring are identified and listed in the public registers of the Positive Drug List (PDL).

The Council is empowered to impose a mandatory therapy monitoring requirement, based on the same conditions and criteria, for medicinal products used in combination or as therapeutic alternatives.

Data collected from designated medical establishments responsible for monitoring the therapeutic effects of medicinal products are processed by the National Council. The NCPRMP (National Council for Pricing and Reimbursement of Medicinal Products) analyzes the reported data obtained from hospital information systems, performing statistical analysis and aggregation for Annex 1 of the PDL (medicinal products used in ambulatory treatment) and Annex 2 of the PDL (medicinal products utilized in the treatment of malignant diseases within hospital care).

Regular analysis of the reporting data's quality and resolution of any discrepancies identified during data verification are conducted by the National Council. Accurate data collection is vital to ensure accurate and meaningful interpretation of the collected information.

Specialized module implemented

The National Council has successfully implemented a specialized module to monitor the therapeutic effects of innovative medicinal products in designated medical establishments across Bulgaria, including complex oncology centers. Through this module, data is collected via hospital information systems, ensuring patient privacy through anonymization, and transmitted to the NCPMP's dedicated server. The Danny platform, known for its capabilities in collecting, processing, and structuring large volumes of medical data, is utilized to extract data. Leveraging SAP HANA technology, the platform enables real-time processing of data, allowing for the generation of valuable insights on treatment outcomes and therapy effectiveness.

The collected statistical information is processed and analyzed. The Council shall provide the information to the National Health Insurance Fund and the Ministry of Health with a view to taking well-founded decisions for the purpose of efficient and appropriate use of public funds. The data obtained this year from the follow-up of the effect of therapy show that the Republic of Bulgaria is very well prepared for the effective implementation of new therapies with real-life effects similar to the studies on the basis of which they are authorized for use under a centralized procedure.

In spite of the difficulties encountered in monitoring the effects of drug therapy, Bulgaria ranks among the few Member States that collect and analyze real-world data. In this sense, our country embarked on the path of evidence-based medicine. Awareness of the need to follow up the "life" of new medicines in real practice is linked to taking serious responsibility in making sound and evidence-based decisions.

The development and enhancement of therapy effect monitoring processes in Bulgaria precede several global initiatives launched at the European level. One such process, initiated in 2019, focuses on harnessing the potential of "big data" and exploring its regulatory implications. Vast amounts of data are generated daily, presenting opportunities for supporting the regulation of medicinal products. In response, the European Medicines Agency (EMA) and the Heads of Medicines Agencies (HMA) have established a collaborative working group to outline the design of "big data" from a regulatory standpoint and identify practical steps for leveraging this data to foster innovation and public health in the European Union (EU). Increasingly, regulatory authorities will rely on insights derived from large datasets to assess the benefit-risk profile of medicines throughout their lifecycle.

APPROVAL OF PHARMACOTHERAPEUTIC GUIDELINES

The Council is responsible for issuing Regulations pertaining to the establishment of pharmacotherapeutic guidelines. These guidelines encompass treatment algorithms and criteria for evaluating therapy outcomes using medicinal products. They form an integral part of the therapeutic strategy funded by the National Health Insurance Fund, ensuring a consistent approach to similar clinical cases. Expert boards within relevant specialties primarily develop the draft guidelines. After conducting a public consultation involving all stakeholders, the Council approves the proposed guidelines, which are subsequently published in the Official Gazette.

The Medicinal Products in Human Medicine Act entrusts the Council with the authority to endorse, revoke or modify pharmacotherapeutic guidelines.

The endorsement, revocation or modification of pharmacotherapeutic guidelines are carried out by Ordinances and, to date, guidelines in 25 clinical specialties have been adopted as follows:

1. pharmacotherapeutic guideline to nuclear medicine;
2. pharmacotherapeutic guideline for the treatment of allergic diseases;
3. pharmacotherapeutic guideline for clinical hematology;
4. a pharmacotherapeutic guideline to anesthesiology and intensive care;
5. pharmacotherapeutic guideline for eye diseases;
6. pharmacotherapeutic guideline of medical parasitology;
7. pharmacotherapeutic guideline for the treatment of neurological diseases;
8. pharmaco-therapeutic guideline for ear-nose-throat diseases;
9. pharmacotherapeutic guideline to the use of antimicrobial medicinal products;
10. pharmacotherapeutic guideline for pediatric clinical hematology and oncology;
11. pharmacotherapeutic guideline for medical oncology;
12. Pharmacotherapeutic guideline for neonatology;
13. Pharmacotherapeutic guideline in nephrology and dialysis;
14. Pharmacotherapeutic guideline in rheumatology;
15. pharmacotherapeutic guideline for the treatment of gastroenterological diseases;
16. pharmacotherapeutic guideline for endocrinology and metabolic diseases;
17. pharmacotherapeutic guideline for the treatment of immune-mediated diseases;
18. pharmacotherapeutic guideline for the treatment of urological diseases;
19. pharmacotherapeutic guideline for pneumology and phthisiology;
20. pharmacotherapeutic guideline for skin and venereal diseases;
21. pharmacotherapeutic guideline for the treatment of infectious diseases;
22. pharmacotherapeutic guideline for pediatrics;
23. pharmacotherapeutic guideline in clinical toxicology - antidote therapy;
24. pharmacotherapeutic guideline for mental diseases;
25. pharmacotherapeutic guideline in obstetrics and gynecology.

Currently, only the pharmacotherapeutic guidelines in transplantology and cardiology have not been adopted.

Drafts of both pharmacotherapeutic guidelines are in the process of being prepared and adopted.

E-GOVERNMENT. INFORMATION SYSTEMS

The implementation of e-government in the NCPRMP incorporates contemporary concepts and adopts an integrated approach, encompassing the following elements:

- Unified National Web Portal;
- Electronic public registers, including a Register of National Identification Numbers for Medicinal Products;
- Interoperability and information interoperability;
- Inter-registry exchange, through implemented web services;
- Electronic administrative services and workflows;
- Specialized module for tracking the effect of therapy.

Web portal for pricing and reimbursement of medicines

The National Council has successfully established and operates the Unified National Web Portal for pricing and reimbursement of medicines (<http://portal.ncpr.bg>), which serves as a centralized platform for all stakeholders involved in the pricing and reimbursement process of

medicines, including government institutions, businesses, and citizens. This web-based portal incorporates advanced technological solutions, including:

- Streamlined data processing for pricing and reimbursement, promoting the "Once Only Principle" to eliminate redundant data entry and enable data reusability.
- Efficient maintenance and regular updates of electronic public registers.
- Provision of electronic administrative services specifically designed for the pharmaceutical industry, facilitating seamless interactions.
- Effective electronic management of administrative business processes, enhancing overall efficiency.

The information system of the NCPRMP has incorporated an advanced feature that enables the linking of the national number with the GTINs of medicinal products. This linkage is facilitated through the submission of data by Marketing Authorization Holders and parallel import authorization holders to the Specialized Electronic System for Tracking and Analysis of Medicinal Products (SESTA). The availability of this integrated information offers several valuable opportunities, including:

- Utilizing the full range of functions provided by the implemented mobile application for accessing medicinal product prices.
- Supporting administrative processes related to data management and facilitating inter-registry data exchange across different institutions.
- Ensuring the secure operation of the National Health Information System (NHIS), particularly concerning the issuance of electronic prescriptions.
- Facilitating the adoption of unified and standardized data nomenclatures within the healthcare system.

By closely monitoring and evaluating the impact of information and communication technologies and e-services on organizational processes, such as efficiency, quality, and effectiveness, the NCPRMP has successfully reduced the administrative burden experienced by both citizens and businesses. This achievement reflects the council's commitment to leveraging technology to streamline operations and improve overall service delivery.

Register of national identification numbers for medicinal products

The Council has implemented an enhanced registry of national numbers within its existing information system. This registry, built on a versatile technology framework, adopts open source and machine-readable data formats. The architecture of the Register of National Identification Numbers for Medicinal Products is designed to ensure consistency in nomenclatures and unified data across all medicinal products.

The comprehensive Register of National Identification Numbers encompasses all authorized medicinal products available within the country, regardless of whether they hold national or centralized authorization, and regardless of their pricing status for the Bulgarian market.

Open to the public, the Register of National Identification Numbers for Medicinal Products consolidates data from the Positive Drug List, the Register of Approved Ceiling Prices of Medicinal Products, and the Register of Maximum Selling Prices of Medicinal Products.

Each medicinal product is assigned a unique national number, serving as a numeric identifier that extends to the level of final packaging. This number offers additional information such as the current ceiling or registered price (for priced medicines), registration number, Anatomical Therapeutic Code (ATC), International non-proprietary name (INN), type of medicinal product, prescribing regimen, and Marketing Authorisation Holder.

The National Identification Number ensures the distinct identification of each medicinal product and is utilized by medical professionals, healthcare establishments, institutions, and all relevant healthcare databases and documentation.

The Register of National Numbers undergoes regular updates by the NCPRMP on the 2nd day of each month, incorporating processed unstructured information provided by the Bulgarian Drug Agency. These updates include new medicinal products and modifications to existing data.

With its unique identifier for each medicinal product and the implemented database, the NCPRMP facilitates electronic management and seamless interoperability with other registries and systems within the healthcare sector. The Council's database information infrastructure encompasses various systems, including:

- The electronic system for purchasing medicinal products for medical institutions in the Republic of Bulgaria.
- The Specialized Electronic System for Tracking and Analysis of Medicinal Products (SESTA) of the Bulgarian Drug Agency.
- The National Register for Diabetes Patients managed by the National Centre for Public Health and Analyses.
- Integration of registries with the National Health Information System in collaboration with Information Services JSC.
- Integration with software companies responsible for hospital and pharmacy information systems under the National Health Service Initiative (NHSI).
- The National Health Information System, which encompasses electronic prescriptions and medical dispensing protocols.
- The system managing medicines paid for with public funds, administered by the National Health Insurance Fund.
- Hospital information systems.
- Pharmacy software.

Through these interconnected systems, the Council ensures efficient data management and supports seamless integration across various healthcare domains.

Interoperability. Web services

The NCPRMP has achieved "System-to-System" interoperability through the implementation of web services, enabling real-time exchange of "live data." This interoperability fosters collaboration among government entities, facilitating the attainment of common objectives and shared responsibility in delivering public services within the realm of drug regulation.

The introduction of the national code represents a significant milestone in the digitalization of public health systems, aiming to enhance data sharing and quality for improved analysis of cause and effect.

All information systems within the healthcare sector rely on the medicines data maintained by the NCPRMP, accessing real-time information through web services.

The availability of machine-readable data has paved the way for the development of an e-prescription prototype, which forms an integral part of the ongoing System Implementation Project of the National Health Information System.

Electronic public registers:

The National Council on Prices and Reimbursement of Medicinal Products (the Council) has implemented a Web portal that provides access to the applications of the Positive Drug List of Medicinal Products, the Register of Approved Ceiling Prices of Medicinal Products and the Register of Maximum Selling Prices of Medicinal Products.



Link to the Portal: <https://portal.ncpr.bg/registers/>

The Portal provides easy access to data on medicinal products through the "Search" and "Advanced Search" functionality in the electronic public registers according to different criteria.

The "Search" feature allows users to access various data through the following options:

- Comprehensive search across all registers or selection of specific registers
- Search based on the trade name of the medicinal product
- Search based on the International Nonproprietary Name (INN)

The "Advanced Search" functionality accesses data on:

- All registries or a specifically selected registry;
- Trade name of the medicinal product;
- International Nonproprietary Name (INN);
- ICD Code;
- ATC Code;
- Manufacturer;

- Marketing Authorisation Holder (MAH);
- Payment level;
- Dosage form;
- Final packaging;
- Change of price and change of reference value of the medicinal product, etc.

The National Council shall update the data on medicinal products in the electronic public registers on the 2nd of each month.

POSITIVE DRUG LIST (PDL)

Annex 1 - medicinal products that are prescribed by the attending physician for ambulatory treatment of insured patients and are paid in full or in part with public funds from the NHIF.

To facilitate prescribing, in the annexes of the Positive Drug List, in the group of medicinal products with the same INN and dosage form, the reference medicinal product (carrier of the lowest value in the group) is marked in a different color, which enables the physician to unambiguously identify the cheapest product in the medicinal group (Fig. 2).

Актуализация на регистрите към: 02.11.2022

Регистър Приложение № 1 надзорен номер Търговско наименование INN

Начало Търси

Резултати

Номенклатура вид на лекарствен продукт
Позитивен лекарствен списък, Приложение № 1

INN	Лекарствен продукт, приетостта на разрешение за употреба	ATC	INN	DOO	Цена търговец на едро	Цена търговец на дребно	РФ. СТ. СТ. 38 DOO	СТ. СТ на ОП на БЗС РФ. СТ. СТ	Ниво на заплащане в %	СТ. СТ на заплащане в лв	Дата на актуал
СЪСТАВЪТ ВХОДИ В КАТЕГОРИЯТА											
17421	Kardolite. Film-coated tablet, 5 mg. Pack: 30 (in blister) (Нобел Фарма ЕООД, България)	C07AB07	Aspirin	10 mg	-	5.21	0.88533	0.69	50	0.40	02.08.2022
17432	Kardolite. Film-coated tablet, 10 mg. Pack: 30 (in blister) (Нобел Фарма ЕООД, България)	C07AB07	Aspirin	10 mg	-	7.98	0.88533	1.98	50	0.99	02.08.2022
28787	Kardolite. Film-coated tablet, 2.5 mg. Pack: 30 (in blister PVC/PVDC/Al) (Нобел Фарма ЕООД, България)	C07AB07	Aspirin	10 mg	-	3.84	0.88533	0.50	98	0.28	02.08.2022
28800	Risopret. Film-coated tablet, 5 mg. Pack: 30 (in blister PVC/PVDC/Al) (Борда Медицинска ЕООД, България)	C07AB07	Aspirin	10 mg	-	4.44	0.88533	0.69	50	0.40	02.08.2022
2782	Тривалковит. Таблет, 10 mg. Pack: 30 (Пакет № V, надзорен номер)	C07AB07	Aspirin	10 mg	-	1.98	0.88533	1.98	98	0.99	02.08.2022

Fig. 2. Illustration of the way of displaying the reference medicinal product in the groups of Annexes 1, 2, 3 of the PHS

Annex 2 - This section comprises medicinal products that are covered by the National Health Insurance Fund (NHIF) but are not included in the cost of medical services provided. It specifically applies to the treatment of malignant diseases in hospital settings, as well as medications used for life-threatening haemorrhages and emergency surgical and invasive interventions in patients with congenital coagulopathies. Additionally, this annex includes medicinal products that are paid by medical institutions with state and/or municipal involvement and are part of the cost of the clinical pathway.

Annex 3 - The medicinal products listed in this annex have a reimbursement level of 100% and are funded by the Ministry of Health (MoH) budget.

Annex 4 - This section encompasses all the medicinal products found in Annex 1, 2, and 3 of the Positive Drug List (PDL). It provides information on the marginal price for each element, including the manufacturer's price, wholesaler's price, and retailer's price. These prices listed in the PDL serve as the maximum prices for the sale of these medicinal products in the open market.

REGISTER OF APPROVED CEILING PRICES OF MEDICINAL PRODUCTS SUBJECT TO MEDICAL PRESCRIPTION

The ceiling price refers to the maximum price set for a medicinal product that requires a medical prescription but is not included in the Positive Drug List (PDL). These prices represent the highest amount permitted for the retail sale of these medications.

REGISTER OF MAXIMUM SELLING PRICES OF MEDICINAL PRODUCTS (OTC)

The maximum retail price for over-the-counter (OTC) medicinal products is determined by the Marketing Authorisation Holder (MAH) and registered by the Council. These prices represent the highest allowable amounts for the sale of these medicines to the public.

REGISTER OF NATIONAL IDENTIFICATION NUMBERS FOR MEDICINAL PRODUCTS

The Register of National Identification Numbers for Medicinal Products encompasses data on all authorized medicinal products in the Republic of Bulgaria, including those with and without established prices by the Council.

In compliance with Bulgarian legislation, the sale of a medicinal product within the country is only permitted after the Council's decision on price approval or registration (excluding specific cases defined under Article 9 and 266a of the Medicinal Products in Human Medicine Act).

The Register of National Numbers consolidates information from the Positive Drug List, the Register of Approved Ceiling Prices of Medicinal Products, and the Register of Maximum Selling Prices of Medicinal Products.


A key objective of this register is to generate and maintain a unique national number for each medicinal product. This identifier is utilized by medical professionals, healthcare institutions, and databases in the healthcare sector, as well as in medical documentation related to medicinal products. The national number ensures the unique identification of medicinal products and in practice represents the NIN of each medicinal product up to the level of final packaging.

Furthermore, the register features a "Search" functionality (Fig. 3), enabling users to search using various criteria such as:

- The national number;
- Trade name;
- Marketing Authorisation Holder;
- ATC Code;
- International Nonproprietary Name (INN);

- Mode of dispensing;
- The ability to sort results based on different criteria.

<https://portal.ncpr.bg/registers/pages/register/list-medicament7.xhtml>



Актуализация на регистрите към: 02.11.2022

Национален номер INN
 Търговско наименование Режим на отпускане:
 Притежател на разрешението за употреба Статус НСЦРП: Сортирай по:
 АТС Код

Резултати

Регистър на националните номера за идентификация на лекарствени продукти

Нац. №	Регистрационен номер, вписан в РУ	Лекарствен продукт	ПРУ	АТС	INN	Режим на отпускане	Статус	Дата на актуал
704	2866072/	[131 I] Meta-Iodobenzylguanidine for diagnostic use. Solution for injection, 37 MBq, Pack: 1 (Vial)	GE Healthcare Buchler GmbH & Co.	V09X02	Iodobegane (131 I)	По лекарско предписание	Цена	28.03.2022
1688	28190278/	[¹⁸ F] FDG/BIODOSMOS. Solution for injection, 44-6807 MBq/ml. Pack: 1 многодозов флакон съдържа 0.2 до 20 ml разтвор, отговарящ на 704 до 138740 MBq по време на калибриране (Vial, colourless-glass class I)	BIODOSMOS S.A.	V09X04	Fludeoxyglucose (¹⁸ F)	По лекарско предписание	Цена	11.04.2022
1191	28000369/	5-Fluorouracil Ebewe. Concentrate for solution for infusion, 50 mg/ml - 20 ml, Pack: 1 (Vial, dark glass type I)	Ebewe Pharma GmbH, H. Fg. KG,	L01BC02	Fluorouracil	По лекарско предписание		16.06.2022
863	28000369/	5-Fluorouracil Ebewe. Concentrate for solution for infusion, 50 mg/ml - 5 ml, Pack: 5 (Ampoule, glass)	Ebewe Pharma GmbH, H. Fg. KG,	L01BC02	Fluorouracil	По лекарско предписание		16.06.2022
2176	28000369/	5-Fluorouracil Ebewe. Concentrate for solution for infusion, 50 mg/ml - 10 ml, Pack: 10 (Vial, dark glass type I)	Ebewe Pharma GmbH, H. Fg. KG,	L01BC02	Fluorouracil	По лекарско предписание		16.06.2022
1190	28000369/	5-Fluorouracil Ebewe. Concentrate for solution for infusion, 50 mg/ml - 10 ml, Pack: 1 (Vial, dark glass type I)	Ebewe Pharma GmbH, H. Fg. KG,	L01BC02	Fluorouracil	По лекарско предписание		16.06.2022

Fig.3 Representation of the search functionalities of the Register of National Medicines Identification Numbers

In the Register of National Numbers, clicking on a medicinal product labelled with a price provides up-to-date information on the price, as well as on the International non-proprietary name (INN), type of medicinal product, mode of dispensing, MAH, reimbursement value and other data (Fig. 4).

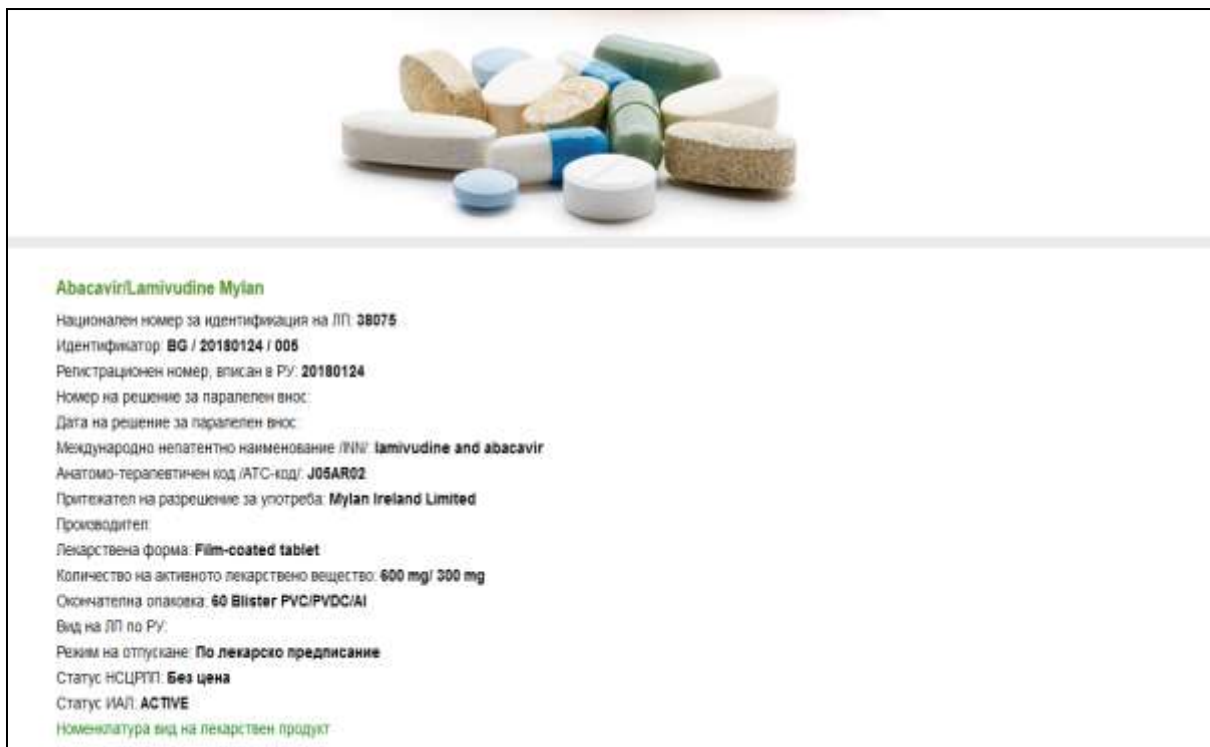


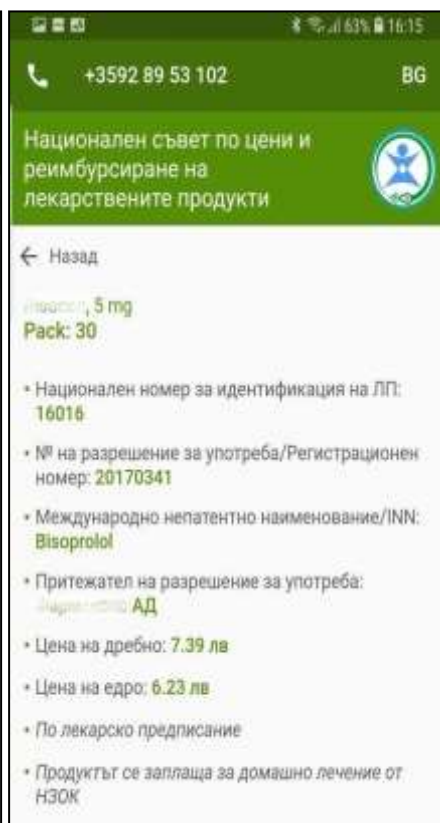
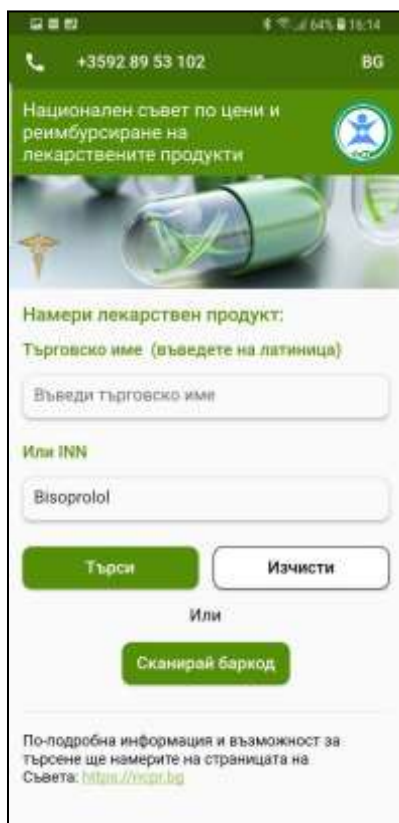
Fig.4 Image of the medicinal product information from the Register of National Identification Numbers for Medicinal Products

The database of all electronic public registers for medicinal products maintained by the Council is the basis for the creation, functioning and updating of the Specialized Electronic System for tracking and analysis of medicinal products included in the Positive Drug List of the Republic of Bulgaria (through which the availability of medicinal products in the commercial network is monitored), the electronic prescription, the Electronic System for purchase of medicinal products for the needs of medical institutions in the Republic of Bulgaria.

Mobile application (DrugPrices.bg) for access to data on medicinal products

A challenge for the Council in 2022 was the implementation of new functionality in the refreshed mobile app providing the ability to check the price of a medicinal product by trade name or International Non-Patent Name (INN), with the additional capability to scan a bar code on the packaging of the medicinal product obtained from the camera of the mobile device. When accessing the extended data for a medicinal product, information on the prescribing method is provided, as well as information on the payment of the medicinal product by the NHIS.

Currently, the feature to scan barcodes from medicinal product packaging is exclusively available for products included in the Positive Drug List (PDL) and reimbursed through public funds. This limitation is due to the GTINs of such products being registered in the SESTA system. By utilizing real-time data from public registers, the mobile application empowers citizens with direct control over monitoring medicine prices within the pharmacy network.



Users can download the app for free via Google play for Android and Apple operating systems.

State Hybrid Private Cloud

The NCPRMP database is securely hosted and operated on the State Hybrid Private Cloud, which serves as a centralized state information infrastructure. This advanced cloud system offers a range of physical and virtual resources exclusively dedicated to the Council's use. With its robust security measures, reliable performance, and user isolation capabilities, the State Hybrid Private Cloud guarantees protection against unauthorized access and ensures the smooth functioning of the system without any interference or compromise to the valuable information resources.

IMPLEMENTED QUALITY MANAGEMENT SYSTEMS. NCPRMP - holder of the label "Effective CAF user"

The policy on quality management in the public administration has been set as one of the main priorities for development of the National Council. It focuses on the implementation of quality management systems to continuously improve the performance of the administration.

Implementing and effectively maintaining a quality management system

The NCPRMP is dedicated to continuously improving its operations and achieving outstanding societal outcomes, aligning with the principles of Total Quality Management (TQM) in the public sector.

In 2019, the NCPRMP embarked on a significant initiative by introducing the European Quality Model CAF (Common Assessment Framework) as a comprehensive tool for analyzing all crucial aspects of the organization. This framework enables thorough assessment and strategic planning to drive organizational improvement and contribute to the realization of "good governance" in public administration.

As a forward-thinking and ambitious administration, the National Council embraced the challenge of implementing the CAF model within the organization under the project "Introduction of the Common Assessment Framework (CAF) in the Bulgarian Administration."

Through an external evaluation, the NCPRMP has been recognized as an "Effective CAF User." This prestigious designation reflects the organization's commitment to quality management as demonstrated by the successful implementation of the CAF system. The evaluation was conducted by an independent expert from the CAF Resource Centre, who highly evaluated the NCPRMP's adoption of the CAF model across all key operational areas. The "Effective CAF User" label not only signifies the organization's remarkable progress through CAF implementation but also acknowledges the collective efforts of management and employees in embracing this model.

HONOURS AND AWARDS

Public Administration Award for significant contribution to the development of information and communication technologies

At an official award ceremony of the Bulgarian Association for Information Technology (BAIT) for 2016, the National Council on Prices and Reimbursement of Medicinal Products was awarded with the State Administration Award for a significant contribution to the development of information and communication technologies, for an implemented project in the administrative service to citizens and businesses, for improving the business environment and achieving publicity and transparency of the work of the administration as a whole.

Award of the Bulgarian Association for Information Technology (BAIT) "Innovation in State Administration"

At an official award ceremony of the Bulgarian Association for Information Technology under the patronage of the President of the Republic, which was held in 2017, the NCPMP was awarded the "Innovation in State Administration" Award for State Administration for a significant contribution to the development of information and communication technologies, for an implemented project in administrative services to citizens and businesses, for improving the business environment and achieving publicity and transparency of the work of the administration as a whole.

European Public Sector Award (EPSA2019)

One of the great achievements of the National Council is the international award for the best European Public Sector Award (EPSA2019). The recognition is a result of the participation of the NCPMP in the European Institute of Public Administration (EIPA) competition, where the Council presented the project "National Information System on Pricing and Reimbursement of Medicinal Products in the Republic of Bulgaria" and was awarded as Best Practice in the category "European/National Project". The award ranks the National Council on Prices and Reimbursement of Medicinal Products among distinguished institutions such as: the Ministry of the Interior of Luxembourg; the Ministry of Finance of Austria; the Ministry of the Interior of the Netherlands; the Supreme Court of Slovenia; the Federal Anti-Corruption Bureau of Austria and others. The main theme of the selection is "New solutions to complex challenges - A public sector citizen-centric, sustainable and fit for the future". Under this title, EPSA 2019 honors those practices that offer new solutions in the field of public services and policy development to address the complex challenges facing the public sector in Europe - demographic change, climate change, technological transformation, cybersecurity and more.

DEVELOPMENT OBJECTIVES AND GUIDELINES

NCPMP aims to sustainably regulate processes and resources within the healthcare system, with a specific focus on medicines. This objective involves addressing the health concerns of the nation by ensuring fair and accessible availability of medicines, improving the regulatory framework through systematic enhancements, internal harmonization, realistic prioritization, quality control, and efficient utilization of public resources.

An important aspect of this effort is to enhance the integrity, structure, and efficiency of the national health system's management. This entails fostering effective coordination and interaction between different levels and sectors, particularly in the realm of medicinal products.

Furthermore, there is a desire to cultivate a new societal and individual mindset regarding health, recognizing it as both a right and a personal responsibility.

The creation and maintenance of a sustainable environment heavily rely on the fundamental characteristics of medicinal products. These products are essential for sustaining life, enhancing its quality, and alleviating suffering. As a result, it is crucial to ensure equal access to medicinal products for all citizens based on their specific needs, regardless of their financial resources. However, the use of medicines necessitates specialized professional expertise and should not be solely determined by the individual's discretion.

To foster and uphold a sustainable environment, the following considerations should be taken into account:

- Existing evaluation criteria should be employed to assess health technologies, including new medicines, based on their clinical, economic, and social benefits. This evaluation helps guide pricing and reimbursement decisions.
- The pricing of medicines should be tailored to the economic context of the country in which they are marketed. Prices should align with the therapeutic value they provide to patients, while also ensuring patient access, sustainable healthcare, and rewarding innovation.
- Transparency should be enhanced, and voluntary cooperation among Member States on pricing and reimbursement should be increased. This collaborative approach ensures the sustainability of health systems and upholds the right of European citizens to access quality healthcare.
- Measures should be developed to guarantee patient access to medicines at affordable prices, ensuring societal benefits and preventing adverse effects on healthcare budgets. These measures may include horizon scanning, early dialogue, innovative pricing models, voluntary joint procurement, and cooperative price negotiations.
- Health Technology Assessments (HTA) and the monitoring of treatment outcomes should be established as vital tools to enhance access to medicines. They contribute to the sustainability of national health systems, incentivize innovation, and provide patients with access to therapies of high therapeutic value.
- Effective controls should be in place to regulate the prices of medicinal products, aligning them with prices in reference countries. Additionally, regulatory legislation compliance should be ensured within the Council's jurisdiction, as stipulated in the Medicinal Products in Human Medicine Act.

To effectively create and uphold a sustainable environment, the following implementation priorities are emphasized:

- Ensuring fair and equitable access to medicines.
- Establishing a regulatory framework that promotes sustainability for patients, healthcare institutions, and the pharmaceutical industry.
- Improving pricing mechanisms to align with sustainability goals.
- Promoting rational use of medicines and appropriate therapeutic decision-making to enhance health outcomes.
- Strengthening and sustaining the development of Health Technology Assessment (HTA) and outcomes monitoring, optimizing the allocation of public funds.

- Ensuring access to quality and effective medicines.
- Contributing to a sustainable environment by mitigating and preventing potential shortages of medicines.

CONCLUSION

The establishment and evolution of the Council align with the emerging global challenges, necessitating a swift reevaluation of work processes, embracing modernization, and embracing digital transformation within its public functions.

One of our utmost responsibilities is to foster unity and work cohesively towards enhancing transparency and efficiency in the regulation of medicines. This endeavor aims to create a more sustainable regulatory environment and ensure fair access to medicines for the citizens of Bulgaria.

The accomplishments attained over the past decade would not have been possible without the concerted efforts of the Council's members and staff, external experts, the Ministry of Health's support, the regulatory authorities of EU Member States, and the invaluable collaboration of the National Health Insurance Fund (NHIF) and the Bulgarian Drug Agency (BDA), who are valued partners of the Council.

Regulatory and normative documents:

- Medicinal Products in Human Medicine Act (SG No. 31 of 13 April 2007);
- Ordinance on the Terms, Rules and Procedure for Regulation and Registration of Prices for Medicinal Products, adopted by PMS No. 97 of 19 April 2013;
- Rules of Procedure of the National Council on Prices and Reimbursement of Medicinal Products and its Administration;
- Council Directive 89/105/EEC of 21 December 1988 on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of National Health Insurance Systems, which is a framework directive.

Official web pages and useful links:

NCPRMP, Composition (ncpr.bg)

NCPRMP, Annual Reports, Annual Reports (ncpr.bg)

NCPRMP, Regulations, Ordinances (ncpr.bg)

NCPRMP, Annual Report, Annual Reports <https://www.ncpr.bg/bg/>

NCPRMP, Pricing and Reimbursement <https://www.ncpr.bg/bg/>

NCPRMP, Health Technology Assessment <https://www.ncpr.bg/bg/>

NCPRMP, Monitoring of the effect of the therapy <https://www.ncpr.bg/bg/>

NCPRMP, Pharmacotherapeutic Guidelines <https://www.ncpr.bg/bg/>