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OPEN LETTER

*from the
National Council
on Prices and Reimbursement of Medicinal Products*

*in support of sustainability, expertise and predictability in the performance
of functions in the field of medicinal product regulation*

DEAR LADIES AND GENTLEMEN,

In the context of the administrative reform planned by the Government, and in the absence of a functional analysis of the current state of the National Council on Prices and Reimbursement of Medicinal Products (NCPRMP), we consider it necessary to clarify the place and role of the institutional model within the system for pricing and reimbursement of medicinal products in the Republic of Bulgaria.

In recent years, the NCPRMP has not only consistently performed the statutory functions entrusted to it, but has also purposefully developed new areas of expertise and strengthened its administrative and professional capacity. As a result, Bulgaria has secured its place on the European health technology assessment landscape, alongside countries with well-developed capacity and practical experience in applying the European regulatory framework in this field.

The pursuit of improvement through better governance, excellence in public sector digitalisation and higher professional standards has always been a guiding principle in the Council's work. For this very reason, we believe that any change should build on what has already been achieved, preserve the expertise accumulated and create more effective mechanisms in the interests of society and every Bulgarian citizen.

This approach is particularly important in the field of pharmaceutical policy, where in recent years the National Council on Prices and Reimbursement of Medicinal Products has evolved dynamically from an institution whose core functions concerned the pricing and reimbursement of medicinal products into a highly specialised expert and regulatory authority with a broad range of additional statutory responsibilities. **Some of these activities extend beyond the pricing of medicinal products and constitute functions that are new to the healthcare system. They include health technology assessment, monitoring treatment outcomes and analysing real-world healthcare data, generating national identifiers and maintaining electronic public registries of medicinal products, as well as other highly specialised activities.**

We believe that optimisation should be carried out in a manner that does not result in the loss of established expert capacity, the disruption of established processes within the implemented information infrastructure, or the severance of enduring institutional relationships developed

through European professional cooperation mechanisms that are directly relevant to pharmaceutical policy and public health. The sustainability of processes and effective oversight are no less important than administrative efficiency. We therefore consider that, before decisions are taken on the future institutional allocation of these functions, a comprehensive functional and institutional analysis must be conducted, covering not only the size and structure of the administration, but also:

- the actual volume and complexity of the activities performed;
- the expert and administrative capacity required;
- the institutional knowledge and experience accumulated;
- the information systems implemented and the data managed;
- national and European commitments;
- the interdependencies between the individual functions and institutions;
- the risks of interruption or delay to processes;
- the safeguards required to ensure continuity in the event of structural change.

We remain committed to participating in an open dialogue and an in-depth discussion of all possible options for implementing the forthcoming administrative and structural reform. This will make it possible to guarantee the continuity of all activities assigned by statute under the Medicinal Products in Human Medicine Act:

- approval and registration of medicinal product prices, and the inclusion, amendment and removal of medicinal products in the Positive Drug List (PDL);
- maintenance of the reimbursement status of medicinal products in the PDL every three years;
- adoption, repeal or amendment of pharmacotherapeutic guidelines;
- health technology assessment of medicinal products;
- designation of the medicinal products for which treatment outcomes are to be monitored, the monitoring period and the healthcare establishments in which such monitoring is to take place;
- generation of national identification numbers for medicinal products;
- ensuring that the national number is connected to all information systems;
- oversight of the activities of all wholesalers and marketing authorisation holders for medicinal products;
- assistance in negotiating discounts under the Health Insurance Act for medicinal products for which applications for inclusion in the PDL have been submitted;
- information, publishing and research activities relating to pricing, reimbursement and pharmaceutical policy.

ACCUMULATED EXPERTISE AND SPECIALISED ROLE

1. The National Council is Bulgaria's national health technology assessment body

Of particular significance is the capacity developed by the National Council on Prices and Reimbursement of Medicinal Products in the field of health technology assessment (HTA).

Health technology assessment of medicinal products was first introduced in Bulgaria in 2016 through amendments to the Medicinal Products in Human Medicine Act. Pursuant to the regulatory framework, a Health Technology Assessment Commission was established within the National Centre of Public Health and Analyses and commenced its work.

Following subsequent amendments to the Act, responsibility for conducting health technology assessments of medicinal products was assigned to the National Council on Prices and Reimbursement of Medicinal Products with effect from 1 January 2019. This change was driven by the need to define clearly and provide an institutional basis for the close interrelationship between pricing and reimbursement, as well as by the recognition that incorporating HTA as an essential element of the NCPMP's decision-making process required the comprehensive structuring and integration of the interrelated activities.

Under this model, pricing serves as the fundamental starting point for the pharmacoeconomic component of health technology assessment. The existing pricing process should therefore not be viewed in isolation, but as the foundation upon which the assessment of therapeutic effectiveness, pharmacoeconomic analysis, budget impact analysis and subsequent decisions on public funding are built.

It is precisely this interconnection that underpins the institutional decision to integrate HTA into the NCPRMP's work, enabling the individual elements of the process to function as a coherent and mutually reinforcing system from pricing and health technology assessment through to reimbursement decisions.

Assigning HTA to the NCPRMP presented the institution with the challenge of building administrative and expert capacity in a field that was relatively new to Bulgaria, virtually from the ground up. The NCPRMP consequently developed a multidisciplinary team in a consistent manner, including through the training and professional development of young specialists. This created expertise combining knowledge of medicine, pharmacy, economics and HTA methodology, together with the ability to apply European and international experience within the Bulgarian healthcare system.

A key feature of the NCPRMP's operating model is the multidisciplinary composition of the working groups that conduct the assessments. A working group is appointed for each report and includes experts with diverse professional backgrounds-pharmacists, medical specialists with expertise in the relevant disease area, economists and other specialists selected according to the characteristics of the technology under assessment. The subsequent assessment, expert review and validation by the NCPRMP's collegiate body are particularly important to the quality and reliability of the process.

Transparency and accessibility of information

Summaries of the HTA assessments conducted are published to make them accessible to the international professional and expert community. This approach gives international visibility to assessments performed in Bulgaria, facilitates the exchange of expertise and enables Bulgaria's HTA work to be accessed and compared with the practices of other European countries. Transparency and international accessibility thus form part of the institution's overall operating model.

NCPRMP participation at European level in implementing Regulation (EU) 2021/2282 on health technology assessment

The development of the NCPRMP's capacity is not confined to the national level. The Council participates actively in the Member State Coordination Group on Health Technology Assessment and its relevant subgroups. This participation is strategically important, as European HTA policy is undergoing a fundamental transformation following the adoption of Regulation (EU) 2021/2282 on health technology assessment.

The new European framework introduces joint clinical assessments (JCAs) at European level and imposes new requirements on national authorities in relation to expertise, coordination and participation in joint European procedures.

Since 12 January 2025, when the new European framework entered into practical application, the NCPRMP, in its capacity as Bulgaria's national HTA body, has represented the country and participated in the introduction and implementation of joint clinical assessments.

The NCPRMP's participation in the Coordination Group and its subgroups enables Bulgaria not only to apply European rules, but also to contribute to their practical development and to the exchange of expertise at European level. This positions Bulgaria as an active participant rather than a passive recipient of European policies.

The path taken by the National Council demonstrates consistent development: from the statutory assignment of HTA, through the creation of national expert capacity, implementation of a

multidisciplinary assessment model, internal expert validation, transparency and international accessibility, to active participation in the European HTA system.

Institutional models in countries applying HTA in pharmaceutical policy

It should be noted that an analysis of the representation of the 27 Member States in the Health Technology Assessment Coordination Group (HTACG) shows that the predominant model is for participation in joint HTA work to be undertaken through specialised agencies, institutions or other public bodies separate from the ministry of health itself. In this context, the NCPRMP follows established European practice by operating as a distinct expert body representing Bulgaria in health technology assessment at European level.

European Union (EU) and EEA countries applying HTA in pharmaceutical policy

Country	Status of HTA body	Institution / Notes
Austria	Independent body	AIHTA (Austrian Institute for Health Technology Assessment) and GÖG.
Belgium	Independent body	KCE (Belgian Health Care Knowledge Centre) and RIZIV-INAMI.
Bulgaria	Independent body	NCPRMP (National Council on Prices and Reimbursement of Medicinal Products).
Germany	Independent body	G-BA (Federal Joint Committee) and IQWiG (Institute for Quality and Efficiency in Health Care).
Greece	Within Ministry of Health	The HTA Commission operates directly under the Ministry of Health.
Denmark	Independent body	Danish Medicines Council and Danish Healthcare Quality Institute.
Estonia	Independent body	Conducted jointly by the Estonian Health Insurance Fund (EHIF) and the University of Tartu.
Ireland	Independent body	HIQA (Health Information and Quality Authority) and NCPE.
Iceland	Independent body	Landspítali (the National University Hospital) and health-insurance committees.
Spain	Independent body	The REDETS network, including the national agency AETS and regional agencies such as AQuAS.
Italy	Independent body	AIFA (Italian Medicines Agency) and AGENAS.
Cyprus	Within Ministry of Health	The activity is conducted entirely within the Ministry of Health.
Latvia	Independent body	State Agency of Medicines of Latvia (SAMLV).

Lithuania	Independent body	State Medicines Control Agency under the Ministry of Health of the Republic of Lithuania.
Luxembourg	Within Ministry of Health	Conducted by the Medical Evaluation and Control unit (CEM) within social security and the Ministry of Health.
Malta	Within Ministry of Health	Directorate for Pharmaceutical Affairs (DPA) within the Ministry of Health.
Netherlands	Independent body	ZIN (National Health Care Institute).
Norway	Independent body	Norwegian Medical Products Agency (NOMA).
Poland	Independent body	AOTMiT (Agency for Health Technology Assessment and Tariff System).
Portugal	Independent body	INFARMED (National Authority of Medicines and Health Products).
Romania	Independent body	National Agency for Medicines and Medical Devices of Romania (NAMMDR).
Slovakia	Independent body	National Institute for Value and Technology in Health (NIHO).
Slovenia	Independent body	Slovenian Quality Health Care Agency; the activity is being restructured into a centralised HTA body under the new regulations.
Hungary	Independent body	NNGYK (National Centre for Public Health and Pharmacy).
Finland	Independent body	Fimea (Finnish Medicines Agency).
France	Independent body	HAS (French National Authority for Health).
Croatia	Within Ministry of Health	The activity is conducted entirely within the Ministry of Health.
Czechia	Independent body	SÚKL (State Institute for Drug Control).
Sweden	Independent body	TLV (Dental and Pharmaceutical Benefits Agency) and SBU.
Switzerland	Independent body	Split model: the Health Technology Assessment Unit is within the Federal Office of Public Health (FOPH).

Other countries (outside the EU/EFTA)

Country	Status of HTA body	Institution / Notes
United Kingdom	Independent body	NICE (England), SMC (Scotland) and AWTTC (Wales)-global pioneers in HTA.
Australia	Independent body	Pharmaceutical Benefits Advisory Committee (PBAC), a global pioneer in HTA.

The countries in which HTA is conducted by the ministry of health share particular geographical and market characteristics. They are predominantly island states or countries with smaller markets which, owing to their isolation and limited consumption volumes, consistently experience shortages of medicinal products and persistent local deficits of essential therapies. In the other European countries where HTA processes are currently undertaken by the ministry of health (Greece and Croatia), major structural changes are forthcoming. These changes are intended to establish and reform separate, independent HTA bodies that will assume full responsibility for expert assessment, independently of the ministries' political and budgetary functions.

Last but not least, the NCPRMP achieved full membership of the European HTA community in January 2023 by joining the Heads of HTA Agencies Group (HAG). HAG is an independent network bringing together 32 European agencies and institutions working to advance strategic cooperation in health technology assessment. The NCPRMP's membership of HAG further consolidates its position as a specialised national body and an active participant in European HTA cooperation.

2. From Bulgarian innovation to European good practice: using real-world data to evaluate medicinal therapy

In 2020, amendments to the regulatory framework assigned the National Council on Prices and Reimbursement of Medicinal Products responsibility for monitoring the outcomes of medicinal therapy and analysing the information collected on the basis of real-world data (RWD).

In performing this new function, the NCPRMP established and developed a systematic institutional process for collecting, processing and analysing real-world healthcare data, transforming them into an evidence base for evaluating the outcomes actually achieved with medicinal therapies.

In fulfilment of a statutory obligation, the NCPRMP also prepares an annual report analysing the results of treatment-outcome monitoring. These reports summarise and analyse the accumulated real-world clinical information and are submitted to the Ministry of Health and the National Health Insurance Fund. They may be used to inform and develop sectoral policy and to assess whether reimbursement of the medicinal therapies concerned should continue.

The comparative nature of the analyses is also important. Monitoring is not limited to outcomes from newly introduced medicinal therapies; it also covers available therapeutic alternatives, whose outcomes are likewise monitored. This enables comparison of real-world outcomes across different therapeutic approaches and assessment of the new therapy's place relative to existing treatment options.

The data accumulated therefore provide information not only on "how a therapy works" in real-world practice, but also answer the question that is more important from a pharmaceutical-policy perspective: "how does it perform compared with the available alternatives?" Comparative analysis increases the practical value of the evidence generated and supports better-informed judgements concerning the effectiveness of therapies, their place in the treatment pathway and the appropriateness of their public funding.

Outcome monitoring for existing therapies also creates a dynamic comparative evidence base that expands as data accumulate over time. This allows the outcomes of new therapies to be evaluated not in isolation, but in the context of the real-world outcomes achieved with existing therapeutic options.

As data accumulate over time, the annual analyses acquire increasing analytical value and scope. Each successive period expands the evidence base, allowing therapy outcomes to be followed over a longer horizon, trends to be identified and more comprehensive analyses to be conducted. This creates a sustainable mechanism for the continuous accumulation, analysis and use of real-world evidence that builds on the process originally established and enhances its value for pharmaceutical-policy decision-making.

The annual analyses are therefore not one-off assessments, but part of a continuous process of evidence generation in which each successive year supplements and enriches the information already accumulated. This enables more in-depth monitoring of real-world treatment outcomes and provides the competent institutions with an up-to-date, longitudinal evidence base for policy development and decisions on public funding and the continuation of reimbursement for medicinal therapies.

This is an important and innovative step in the development of evidence-based pharmaceutical policy in Bulgaria, as it allows decisions on the public funding of medicinal products to be informed not only by clinical trial data, but also by evidence generated in real-world healthcare settings. This approach places outcomes actually achieved by patients at the centre of the evaluation of medicinal therapies. The development of this system places Bulgaria among the early European adopters of the institutionalised use of RWD to monitor the outcomes of medicinal therapy.

A distinctive feature of the Bulgarian model is its institutional basis. The process is organised and developed by the National Council and encompasses not only data collection, but also the systematic structuring, processing and analysis of information to generate evidence that can be applied in practice. Data from routine healthcare are thereby transformed into a tool supporting pharmaceutical-policy decisions. This distinguishes the Bulgarian approach from the use of RWD solely in individual scientific, academic or industry studies. The importance of the approach has also received international recognition. The Council's practice is presented in the report of the Central, Eastern Europe and Baltics Health Policy Network (CEEBA-HPN), "Human-centric digitalization of healthcare: Building sustainability and resilience through innovation in the CEEBA region" (https://www3.weforum.org/docs/WEF_CEEBA_HP_N_Report_2022.pdf). In the section "Good policy practices in Human-centric digitalization of healthcare from CEEBA-HPN countries", Bulgaria-through its national body, the NCPRMP-is cited as an example of good practice in the use of real-world evidence. This places the Bulgarian model within the broader context of good practice in using digitalisation and health data to improve the sustainability and efficiency of healthcare systems.

Bulgaria's inclusion as an example of good practice in an international comparative report demonstrates that the approach developed by the Council is not merely a national initiative, but also a model for other healthcare systems in the region.

From RWD to real-world evidence (RWE)

The key innovation lies not merely in the availability of large volumes of health data, but in the ability to transform those data into evidence of practical value. Monitoring medicinal-therapy outcomes and analysing the information collected are precisely what turn real-world data into a basis for generating RWE.

This approach makes it possible to observe how a therapy is used under real-world conditions, what outcomes are achieved in patients treated in routine practice and how those outcomes compare with expectations based on clinical trials.

The traditional question, "What do the clinical trials show?", is thus complemented by another equally important question: "What happens to patients in real-world practice?" The answer is crucial to modern pharmaceutical policy.

RWE is particularly important in decisions on the reimbursement of medicinal products where public resources are limited. Clinical trial data remain a fundamental part of medicinal product assessment, but they are generated under controlled conditions and before a therapy is used widely in real-world practice. RWD complement this evidence base with information on patients actually treated and the outcomes actually achieved. This makes it possible to monitor:

- the real-world use of medicinal therapies;
- treatment outcomes in routine practice;
- changes in treatment patterns;
- treatment outcomes over time;
- the characteristics and outcomes of patients treated in routine practice;
- the use of public resources.

Treatment outcome monitoring thus becomes a natural continuation of medicinal product assessment from the initial reimbursement decision to the monitoring of outcomes achieved in real-world practice. This is particularly important for innovative therapies, for which the duration and volume of available data are inevitably limited at the time of initial assessment.

The systematic monitoring launched in 2020 has created not merely a database, but long-term institutional capacity to generate and analyse real-world evidence. As information accumulates, so does the ability to track outcomes over time, identify trends and conduct more in-depth analyses. The model has thus evolved from initial data collection towards analytical processing and the generation of RWE.

The experience accumulated is also relevant beyond the Council's administrative work: Bulgarian real-world data have already been used in scientific research, including studies evaluating the effectiveness of medicinal therapies in Bulgarian patients.

The model applied by the Council clearly demonstrates how digitalisation can be used not only to automate administrative processes, but also to improve the quality of policy and management decisions. This is the essence of human-centred digitalisation: technology and data are not ends in themselves, but means of achieving better health outcomes for patients and more effective management of the healthcare system.

The Bulgarian approach can therefore be regarded not merely as a technological or administrative initiative, but as good practice in public health policy, linking digital health data, real-world treatment outcomes and decision-making processes.

Today, RWD and RWE are increasingly recognised as key tools of modern pharmaceutical policy. Bulgaria, however, began building a practical mechanism for monitoring medicinal-therapy outcomes as early as 2020. This early start, combined with the institutionalisation of the process, the accumulation of real-world data and the development of analytical capacity, creates a significant expert and institutional advantage.

The Bulgarian experience shows that the NCPRMP is not merely following the trend towards the use of RWD and RWE; it has developed its own model for transforming real-world data into evidence supporting pharmaceutical policy and public-funding decisions. In this sense, monitoring medicinal therapy outcomes and analysing the information collected constitute an institutional innovation of long-term significance.

3. Research and international visibility

Drawing on its accumulated expertise and practical work, the NCPRMP has over the years developed substantial research activity in health technology assessment, medicinal-therapy outcome monitoring, real-world data and real-world evidence, and the pricing and reimbursement of medicinal products.

This work has resulted in 47 scientific publications produced in collaboration with national and international research teams including papers in journals with an impact factor and more than 300 citations internationally. These figures are an important indication of the NCPRMP's development as an institution that not only applies science-based methods, but also contributes to the creation and advancement of scientific knowledge in pharmaceutical policy.

The development of research in real-world evidence is particularly significant. Bulgaria's practical experience in collecting and analysing real-world healthcare data enables those data to be used not only for institutional decision-making, but also for scientific analyses and publications. Research is therefore not separate from the Council's core functions, but a natural extension of its day-to-day expert work.

4. A modern digital administration serving citizens, businesses and the healthcare system

Over the years, through comprehensive digitalisation, the National Council has established itself as a transparent, highly specialised and efficient administration operating in a fully digital environment. The public registers maintained by the NCPRMP, including archived data as at each update, are available on the Council's website, ensuring transparency and full process traceability. Web services make these public data available in machine-readable format to software developers. The Council has implemented fourth level electronic administrative services-the highest level for 100% of the services it provides to businesses. A web-based platform enables applicants to submit applications and monitor deadlines, providing an objective and tangible reduction in the administrative burden on businesses. The "ONCE ONLY" principle is applied: data are collected once and reused across different information systems. A high level of cybersecurity has been implemented, with system data stored in the State Hybrid Private Cloud. A mobile application for medicinal product prices is also operational, enabling citizens to report sales above the maximum price directly to the relevant Regional Health Inspectorate.

5. Digital infrastructure for the unique identification and traceability of medicinal products

By an amendment to the Medicinal Products in Human Medicine Act, promulgated in State Gazette No. 103/2020, the legislature replaced the administrative body originally designated to generate a unique national identification number for each medicinal product in the Republic of Bulgaria-the Bulgarian Drug Agency and assigned to the National Council on Prices and Reimbursement the generation of such numbers and the creation and maintenance of a public register of national identification numbers for medicinal products. This ensures the unique identification of every medicinal product authorised for use in the Republic of Bulgaria, down to the final pack level, as well as the interoperability of healthcare information systems.

Although the primary information on medicinal products authorised and registered in the Republic of Bulgaria, as well as medicinal products authorised under the centralised procedure pursuant to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency, is created and maintained by the Bulgarian Drug Agency, this responsibility was assigned to the National Council on Prices and Reimbursement of Medicinal Products on the grounds that it already had a highly effective information system that could be upgraded relatively quickly for the purposes of the national number (transcript of the 422nd sitting of the 44th National Assembly, 6 November 2020:

<https://www.parliament.bg/bg/plenaryst/ns/55/ID/10508>).<https://www.parliament.bg/bg/plenaryst/ns/55/ID/10508>

In fulfilling these obligations, each month the NCPRMP converts the information received on medicinal products into a structured, machine-readable database the Register of National Identification Numbers for Medicinal Products which is publicly accessible on the Council's website. Through web services maintained by the NCPRMP, this organised database supports the operation of the National Health Information System (NHIS), the Specialised Electronic System for Tracking and Analysis of Medicinal Products (SESPA), and electronic prescriptions. It also

underpins the architecture of the Ministry of Health's centralised procurement system for medicinal products, hospital and pharmacy software, and other systems.

6. The Council actively participates in European cooperation on medicinal product price transparency

EURIPID Collaboration

The National Council on Prices and Reimbursement of Medicinal Products has been a full and active member of the EURIPID Collaboration (Joint Action Agreement on the Pricing and Reimbursement of Medicinal Products) since 1 June 2015.

The EURIPID database provides medicinal product price information from the national competent authorities of 27 European countries, data on sales volumes in the outpatient sector and information on managed entry agreements. It thereby helps to increase transparency in medicinal-product pricing and improve patients' access to necessary treatment.

The NCPRMP participated actively as a partner in the European Union-funded project "Developing early warning features and guidance on pricing through the EURIPID database" (Project 101100610-EURIPID; EU4H-2022-PJ, topic EU4H-2022-PJ-08). The project aimed to increase transparency in medicinal product pricing and cooperation among European countries, explore opportunities to enhance the EURIPID database and extend its functionality, and develop practical guidance for pharmaceutical pricing and reimbursement policies in European countries.

Pharmaceutical Pricing and Reimbursement Information Network (PPRI)

The NCPRMP is a member and active participant in the Pharmaceutical Pricing and Reimbursement Information Network (PPRI), which comprises approximately 90 institutions from 50 countries, including all 27 Member States of the European Union. The network facilitates cooperation among authorities responsible for medicinal product pricing and reimbursement and promotes the exchange of information and experience among public administration representatives, supported by scientific evidence and a shared understanding of pharmaceutical policy issues.

7. The National Council: a driver of digital transformation and innovation in healthcare

In 2026, the Council was approved to participate jointly with the Ministry of Health, as a lead partner, in the Programme "Research, Innovation and Digitalisation for Smart Transformation" 2021–2027, Priority 2: Digital Transformation of the Public Sector; Specific Objective RSO1.2: Reaping the benefits of digitalisation for citizens, companies, research organisations and public authorities (ERDF), for 2025–2027, with the following priority use cases:

- "Pharmaceutical supply-chain management", covering relevant datasets, data quality and accessibility, the structuring of a data space, and supply-chain management needs and readiness;
- "Cancer treatment research"-the creation of a secure data space for generating RWE on cancer treatment and the development of a risk-sharing model based on real-world outcomes of treatment with medicinal products.

The programme aims to contribute to the development of an effective and sustainable ecosystem for data-driven governance and economy by increasing public sector capacity to create and analyse data and supporting the creation of sectoral data spaces, including open data. It provides for strengthening national cybersecurity in order to address crises and emergencies and respond to societal and global challenges. It promotes innovation in key sectors, with healthcare as a priority, and fosters interaction among citizens, businesses, research teams and the public sector to increase transparency and support the transition towards smart, cybersecure governance.

Working meetings concerning the use cases described above were held between the NCPRMP and representatives of a World Bank team. They were based on a conceptual framework setting out the

principal pillars of nine economic sectors in Bulgaria, including healthcare and, specifically, management of the medicinal product supply chain with a view to addressing shortages.

DEAR LADIES AND GENTLEMEN,

In view of the foregoing, and given that the NCPRMP carries out highly specialised expert and scientific work, we call for a thorough functional analysis that fully clarifies the place and role of the regulatory authority in the healthcare system at both national and European level, and for the preparation of a comprehensive concept for reform in the field of medicinal product regulation.

This open letter does not seek to defend an organisational structure for its own sake. Rather, it raises the question of how the State will guarantee the continuity of regulatory processes, transparency, digitalisation, oversight and, above all, Bulgarian patients' access to medicinal therapy.

We believe that this question deserves an open, professional and evidence-based public debate.

During the public consultation on the draft legislative amendments, the Council will adopt an active and responsible position and publicly present its reasoned opinion - in defence of the system's sustainability and, above all, the interests of Bulgarian citizens.

**NATIONAL COUNCIL
ON PRICES AND REIMBURSEMENT OF MEDICINAL PRODUCTS**

31 August 2026