

Analysis of medicinal product shortages in Bulgarian hospital settings in 2023: addressing procedures and unmet needs

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Abstract

Objective: This study aims to examine the national landscape of medicine shortages in Bulgaria, with an emphasis on the supply and procurement of medicines requested by hospital facilities due to their absence from the domestic market.

Materials and methods: A mixed-method approach was employed, combining regulatory and real-world data analysis. European and national legislation governing the supply of unavailable medicines in Bulgaria, including the Medicinal Products in Human Medicine Act and Ordinance No. 10, were reviewed. Data on unavailable medicinal products imported into Bulgaria in 2023 were obtained from the Bulgarian Drug Agency. These data were categorized into therapeutic classes, dosage forms, and regulatory pathways, with additional analysis of price regulation and World Health Organization Essential Medicines List status.

Results: In 2023, Bulgaria imported 165 INNs that were unavailable through the standard supply chain and reimbursement system due to their absence from the local market. Of these, 35% were procured under the regulatory framework established by Article 266a of the Medicinal Products in Human Medicine Act. These imports comprised 1,996 deliveries to hospital facilities nationwide. The analysis identified significant shortages in key therapeutic areas, including oncology, cardiovascular care, and critical care. The imported products were predominantly opioid analgesics, anticoagulants, anticancer medications, and diagnostic tools. Notably, several of these medicines are listed in the World Health Organization Essential Medicines List, underscoring their critical importance in addressing unmet healthcare needs.

Conclusion: Medicine shortages in Bulgaria present substantial challenges to healthcare delivery, further complicated by complex regulatory, economic, and market dynamics. Legislative mechanisms could not ensure the availability of some essential medicines. This study highlights the need for comprehensive national strategies to address shortages effectively, drawing on best practices from other European Union Member States. Future research should focus on expanding the assessment of shortages to enhance healthcare resilience and ensure continuous access to essential treatments.

Keywords

commercial factors, drug shortages, imports, patient access to unaffordable medicines

Introduction

According to the EU's pharmaceutical framework (European Commission 2020; European Medicines Agency 2025), medicine shortages have emerged as a significant challenge for healthcare systems across Europe, with implications for patient care, public health, and pharmaceutical supply chains. These shortages – defined as the inability to meet the demand for medicines within a given time frame – affect a wide range of therapeutic areas and are becoming increasingly prevalent (Shukar et al. 2021; Aronson et al. 2023). The underlying causes are complex and multifactorial, encompassing disruptions in manufacturing processes, regulatory issues, economic factors, and market dynamics. In particular, the European context presents unique challenges due to the diverse regulatory frameworks, economic policies, and market structures across Member States.

To support the drug selection process at the national level, the World Health Organization developed the Essential Medicines List (WHO EML), which plays a crucial role in addressing shortages by identifying the most essential medicines that should always be available as part of a functioning health system. This list serves as a global standard for medicine selection, guiding national policies and promoting equitable access to treatments. It is intended to ensure that key medicines across all major therapeutic areas are accessible to all populations, supporting evidence-based and rational prescribing by healthcare professionals (World Health Organization 2025). However, ensuring the availability of all these medicines in small and medium-sized European markets appears challenging. Commercial considerations, such as the need for manufacturers to produce small amounts of country-specific packaging and leaflets, lead to diseconomies of scale in small markets, further decreasing the appeal of marketing products in these countries.

There are additional situations where medicines remain inaccessible to patients without being classified as shortages. Pharmaceutical companies may choose not to launch a medicinal product in certain countries if the market is perceived as insufficiently attractive – particularly due to limited purchasing capacity, as highlighted in a recent EU-level analysis (European Commission 2021). National pricing and reimbursement policies, the organization of health systems, and national administrative procedures related to health technology assessment could also contribute to limited access to medicines and may result in medicine shortages (Vogler 2022; Miljković et al. 2023). Another defining aspect of medicine shortages is the discontinuation of supply for a drug that has already been introduced to the market. This can occur for various reasons, including shifts in market demand, manufacturing issues, regulatory changes, or price erosion. Such discontinuations significantly impact patient care and highlight the complexities of maintaining a stable drug supply chain (WHO Regional Office for Europe 2023). Vogler and Fischer (2020) noted that, to overcome medicine shortages, some measures have been introduced – mostly at the

national level – and that there is a need for cross-country collaboration at the European level to address the issue sustainably. Notably, except for Sweden and the United Kingdom, all European countries with regulated pricing systems employ external price referencing, at least as a supplementary pricing strategy. A recent study by the European Parliament's Science and Technology Options Assessment Panel confirmed that the responsibility for pricing and reimbursement decisions rests with individual Member States, resulting in a complex landscape where pharmaceutical manufacturers make strategic choices that can influence patient outcomes. Delayed or absent product launches in certain countries significantly affect access to medicines, especially in smaller markets and lower-income regions (European Parliament 2023).

To address these challenges, the European Commission adopted a set of pharmaceutical legislative reforms in 2023. These reforms encompass several aspects, including a proposed reduction in the baseline data protection period currently granted to pharmaceutical innovators within the European Union, as outlined in the legislative roadmap and stakeholder analyses (EFPIA 2023; European Commission 2025). However, the new rules offer marketing authorization holders a notable advantage: a 2-year extension of data protection if the innovator launches the product in all Member States (referred to as the “launch condition”). This provision directly affects innovative products; nevertheless, shortages and the inadequate availability of essential medicines remain significant challenges. The European Medicines Agency has undertaken efforts to address medicine shortages, including the establishment of a critical shortages list monitored at the EU level. This list provides detailed information on ongoing and resolved shortages for both human and veterinary medicines. However, the management of shortages for medicinal products that are not centrally authorized remains primarily the responsibility of national competent authorities – particularly when such shortages lack cross-border implications, as reflected in the EMA shortages database (European Medicines Agency 2025).

In Bulgaria, medicinal products within the standard supply chain and included in the reimbursement system are monitored through a national mechanism – the Specialized Electronic System for Tracking and Analysis of Medicinal Products listed in the Positive Medicines List – via the national tracking system (Ministry of Health of Bulgaria 2025). However, medicinal products that are excluded from the reimbursement system or are included solely with a registered price are not tracked within this system. These products are typically requested by hospital facilities under alternative regulatory mechanisms. This distinction presents an opportunity for an in-depth review, as it highlights an important yet underexplored aspect of medicinal product accessibility and supply.

This study focuses on medicinal products that are unavailable on the Bulgarian market not due to quality or supply chain issues, but because of commercial factors such as the absence of a market launch or the perceived unattractiveness of the local market. In this work, the

supply of unaffordable or inaccessible-to-patients medicinal products in Bulgaria is analyzed due to its significant role in addressing unmet medical needs and public health challenges. Bearing in mind that healthcare services are a national priority, we first analyzed national legislation regarding the supply of medicines that are either unavailable or outside the scope of the reimbursement system and then searched for information on the import of such products.

Materials and methods

A mixed-method approach was employed, combining regulatory and real-world data analysis. First, the relevant European and national legislation on the supply of medicines that were not available on the Bulgarian market was analyzed. Through this analysis, Regulation (EC) No. 726/2004 of the European Parliament and of the Council, the Medicinal Products in Human Medicine Act, and Ordinance No. 10 of the Ministry of Health were identified. These regulatory acts establish procedures for products that are typically not accessible through standard prescribing and dispensing processes due to either lack of authorization, absence of product launch, or market withdrawal.

A comprehensive list of medicinal products that were unavailable on the Bulgarian market yet requested by hospital care establishments in 2023 was obtained from the Bulgarian Drug Agency under the Access to Public Information Act. The data were systematically analyzed and categorized into several groups. Key findings were visually represented and are discussed in detail in this article.

Results

European and Bulgarian legislation

The primary legislation regulating medicinal products in Bulgaria is the Medicinal Products in Human Medicine Act. This Act refers to Article 83 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council, which governs the use of unauthorized medicinal products in Compassionate Use Programs (CUPs). Article 266a of the Act specifies that, in cases where no alternative treatment is available for a particular disease in Bulgaria, a medicinal product authorized for use in a European Union Member State may be administered to an individual patient. Although authorized under this law, such products are not distributed on the Bulgarian market. In line with Article 266a, a list of medicinal products approved for the treatment of Bulgarian citizens who lack adequate therapeutic options domestically is established. When a medicinal product is included under Article 266a, it is procured through a special order by a medical institution for hospital care.

The specific regulations for initiating treatment with unavailable medicinal products outside the reimbursement system are outlined in Ordinance No. 10 of 17 November 2011, which establishes the conditions and pro-

cedures for the use of medicinal products not authorized in the Republic of Bulgaria. According to Ordinance No. 10, three pathways for accessing medicinal products without marketing authorization can be identified. The first involves the treatment of a group of patients with a medicinal product for compassionate use, as defined in Article 83 of Regulation (EC) No. 726/2004 of the European Parliament and of the Council. The second concerns the treatment of specific patients with medicinal products that are either unauthorized for use in the Republic of Bulgaria or unavailable within the country due to the absence of a market launch or discontinuation of supply. These products are supplied through a special order from a hospital care facility. Hospital care facilities submit proposals to the Minister of Health for the inclusion of these medicinal products in the list under Article 266a, based on the needs of the patients they are treating. The third pathway concerns the use of a medicinal product that is authorized in the country but administered outside the parameters of its authorization. In all cases, medicinal products that are not authorized for use may be prescribed by a committee of three physicians from the relevant hospital care facility, with at least one member holding a recognized specialty in the disease profile. Additionally, a pharmacist and a lawyer participate in the committee's deliberations. The committee prepares a protocol that must be approved by the Bulgarian Drug Agency (BDA). The BDA is responsible for reviewing these protocols to ensure compliance with legal requirements and for notifying the distributors responsible for delivering the medicinal products.

Import of unavailable and unaffordable medicines

In 2023, a total of 165 INNs corresponding to unavailable medicinal products were supplied in Bulgaria. Of these, 58 (35%) were governed by Article 266a of the Medicinal Products in Human Medicine Act, while the remaining 107 (65%) were not distributed within the country, as illustrated in Fig. 1. These INNs were imported through 1,996 deliveries to hospital facilities.

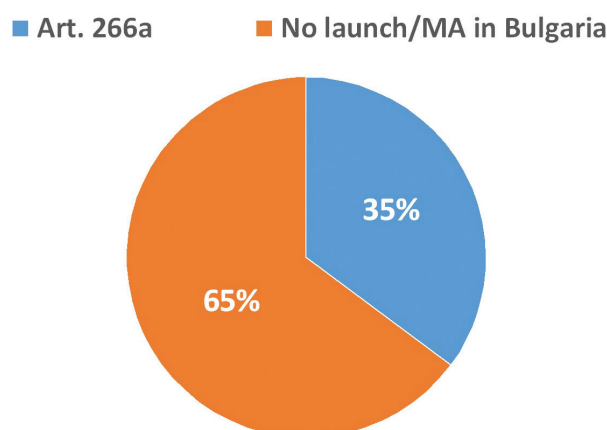


Figure 1. Legislative categories of imported unavailable medicinal products.

Further analysis was conducted on the INNs by using the publicly accessible website of the National Council on Prices and Reimbursement (NCPR) in Bulgaria. This analysis focused on determining the availability of registered prices for the imported medicinal products. The findings indicate that 29 of the INNs are listed either in the annexes of the Positive Drug List, which includes all medicinal products reimbursed through public funds, or in the Register of ceiling prices, which lies outside the reimbursement system. Conversely, many of the INNs ($n = 136$) lack a nationally registered price and are not present on the national market (Fig. 2).

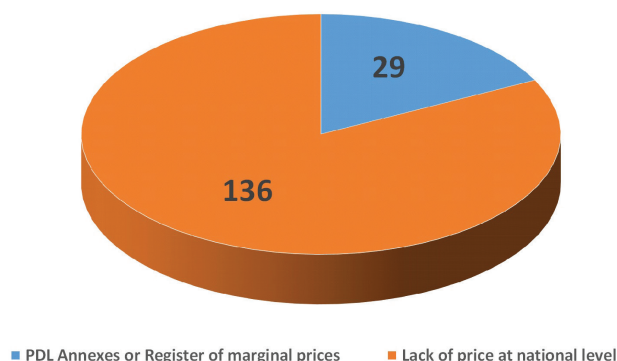


Figure 2. Price regulation status of imported medicinal products.

An analysis of the pharmacological categories of drug shortages (Fig. 3) reveals that opioid analgesics were the most frequently requested, with a total of 334 deliveries. This high volume suggests a significant demand for pain management therapies in Bulgaria, likely due to limited or unavailable alternatives within the country. Other commonly requested products include anticoagulants (206 deliveries), anticancer drugs (198), diagnostic tools (127), and neuromuscular blockers (112). These findings high-

light that the primary drivers of unavailable medicinal product imports in Bulgaria are the unmet needs in pain management, cardiovascular care, cancer treatment, and diagnostic services. The substantial number of deliveries in these categories underscores potential gaps in the availability of approved pharmaceutical options in the national healthcare system.

The quantities of medicinal products are reported based on their respective dosage forms, such as ampoules, vials, and packs. However, the precise quantities of active ingredients for each INN could not be accurately determined due to variations in packaging and the number of dosage units within each product. For example, a single pack may contain 5, 10, or 20 units, depending on the manufacturer or product specifications. To ensure consistency, the quantities were categorized by dosage form as recorded in the available data. While efforts were made to apply standardized definitions for dosage forms, no assumptions were made regarding the specific unit content of packs due to inconsistencies in the supplied information.

The analysis further highlighted disparities in the reported shortages across INNs (Table 1). Fentanyl exhibited the highest recorded quantity at 426, 449, pointing to a notable supply issue for this essential medication. Phytomenadione also demonstrated considerable usage, with 144, 343 units reported in 2023. The quantity of remdesivir (2, 112) indicates ongoing challenges, potentially associated with its role in COVID-19 treatment efforts, underscoring the continued effects of the pandemic on drug availability.

Ten of the medicines currently unavailable through the standard distribution pathway in Bulgaria are included in the WHO EML, emphasizing the severity of these shortages. These medicines are vital for key therapeutic areas, including oncology (e.g., vincristine, melphalan, dacarbazine), cardiovascular treatment (e.g., adenosine, prota-

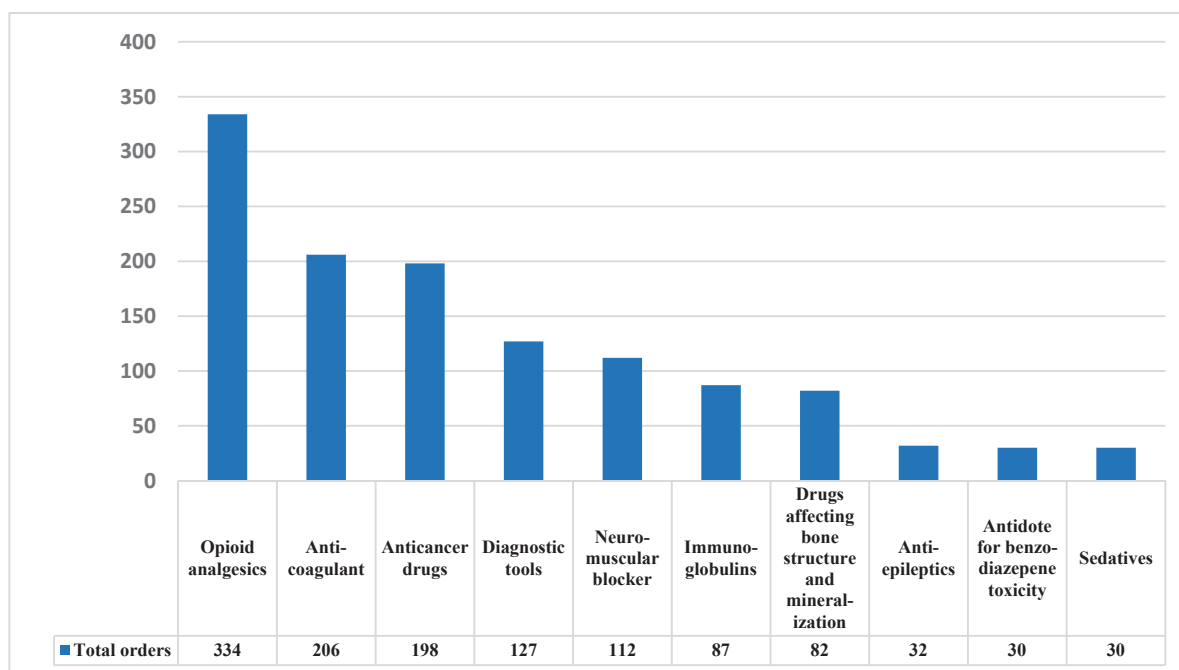


Figure 3. Number of deliveries per pharmacological class of imported unavailable medicinal products in 2023.

Table 1. Most common drug shortages in Bulgaria by INNs.

INN	Dosage form	Quantity	Total delivered quantity	Part of WHO EML
Fentanyl	Vials	2400	426,449	Yes
	Packs	1829		
	Ampoules	422,220		
Phytomenadione	Ampoules	142,380	144,343	Yes
	Packs	1763		
	Vials	200		
Atracurium	Ampoules	33,770	34,710	Yes
	Packs	940		
Rocuronium bromide	Packs	170	32,400	No
	Ampoules	28,230		
	Vials	4000		
Protamine	Ampoules	22,560	23,663	Yes
	Packs	603		
	Vials	500		
Tafamidis	Capsules	7280	7280	No
Perfluorobutane	Packs	1300	6930	No
	Ampoules	1310		
	Vials	4320		
Dexmedetomidine	Ampoules	5470	5937	No
	Packs	467		
Vincristine	Packs	346	5476	Yes
	Ampoules	5130		
Milrinone	Packs	117	5288	No
	Vials	56		
	Ampoules	5115		
Sodium chloride	Ampoules	3800	5203	Yes
	Infusion Bank	1000		
	Vials	300		
	Packs	103		
Immunoglobulins normal human for intravascular administration	Packs	553	4713	No
	Vials	4160		
Ciclosporine	Ampoules	4680	4680	Yes
Dacarbazine	Vials	2970	3170	Yes
	Packs	200		
Sufentanyl	Ampoules	3050	3050	No
Remdesivir	Packs	750	2112	No
	Vials	1362		
Cardioplegia solutions	Bottles	1470	1770	No
	Bags	300		
Melphalan	Ampoules	50	1338	Yes
	Vials	260		
	Packs	1028		
Adenosine	Ampoules	1026	1163	No
	Packs	137		
Fluorescein	Ampoules	1030	1131	Yes
	Packs	101		

mine), critical care (e.g., atracurium, sodium chloride), and supportive therapies such as vitamin K (phytomenadione).

The specific INNs were cross-referenced with the EMA shortages catalogue for the period from January 2023 to December 2023, corresponding to the timeframe of the analyzed data. Notably, none of the INNs identified as unavailable at the national level were listed in the European register of shortages during this period.

A notable pattern in the distribution of unavailable medicinal products across Bulgaria was found (Table 2). The

highest number of deliveries was recorded at the Specialized Hospital for Active Treatment of Pediatric Diseases – Prof. Dr. Ivan Mitev in Sofia, with a total of 253 deliveries. This substantial volume indicates a significant focus on meeting pediatric healthcare needs in the capital, suggesting a prioritization of resources toward pediatric care.

Additionally, the presence of exclusively university-affiliated hospitals among the top ten recipients of these deliveries highlights the centralization of such essential resources within university hospital settings. These institutions serve as key healthcare hubs, reflecting their vital role in providing specialized care. This distribution pattern not only emphasizes the importance of university hospitals in the national healthcare system but also suggests that these centers play a pivotal role in the logistics of distributing high-demand medications.

Discussion

In this work, we sought to identify regulatory and supply issues related to medicine shortages within the Bulgarian market. We identified one European and three national regulatory procedures governing the supply of unavailable medicines. We also found that some of the most essential medicines are absent from the national market, most likely due to financial reasons from the perspective of marketing authorization holders.

Medicine shortages in Bulgaria significantly affect various classes of medications, reflecting a broader issue of access inequity across EU Member States, particularly regarding well-established medicines. The centralized access procedure serves as a streamlined mechanism for the rapid authorization of medicines at the European level. However, following authorization, pharmaceutical companies retain the discretion to determine the markets within the EU where they will distribute their products. Traditionally, negotiations between health authorities and pharmaceutical companies have taken place on an individual basis, as observed in several European pricing strategies (Wenzl and Chapman 2019). Pharmaceutical companies often prioritize entry into larger markets first, primarily because the legislative frameworks and health insurance systems in these regions are more likely to provide reimbursement for new medicines – particularly under evolving market conditions (Leopold n.d.). This approach, while understandable from a business perspective, perpetuates disparities in drug availability, particu-

Table 2. Top 10 deliveries to hospital facilities.

Category	Hospital facility	Number of deliveries
Pediatric hospital	Specialized Hospital for Active Treatment of Pediatric Diseases – Prof. Dr. Ivan Mitev, EAD, Sofia.	253
Emergency hospital	University Multiprofile Hospital for Active Treatment and Emergency Medicine ‘Nikolai Ivanovich Pirogov,’ Sofia	53
Private hospital	Acibadem City Clinic Tokuda Hospital, Sofia	56
Cardiology hospital	Multiprofile Hospital for Active Treatment ‘National Cardiology Hospital,’ Sofia	27
University hospitals (Sofia)	University Multiprofile Hospital for Active Treatment ‘Sveti Ivan Rilski,’ Sofia	74
	University Multidisciplinary Hospital for Active Treatment ‘Aleksandrovska,’ Sofia	61
	University Multi-Profile Hospital for Active Treatment ‘Tsarina Ioanna – ISUL,’ Sofia	28
	University Multiprofile Hospital for Active Treatment ‘Sveti Georgi,’ Plovdiv	170
University hospital (Plovdiv)	University Multiprofile Hospital for Active Treatment ‘Sveti Georgi,’ Plovdiv	170
University hospital (Varna)	University Multiprofile Hospital for Active Treatment ‘Sveta Marina,’ Varna	41

larly affecting smaller markets within the EU. Significant variability remains, with larger, more economically robust markets typically experiencing shorter launch delays due to favorable reimbursement policies and market sizes that are more attractive to pharmaceutical companies. Countries with higher GDPs tend to experience shorter launch delays, suggesting that economic strength is a key factor in accelerating drug availability and highlighting disparities in market access (Büssgen and Stargardt 2022). In cases where authorized treatments are unavailable, insufficient, or do not meet specific patient requirements, access to these medicinal products can offer life-saving or essential therapeutic alternatives. This issue is particularly relevant in Bulgaria, where the healthcare system may rely on these mechanisms to ensure patients receive timely and effective treatments that are otherwise inaccessible.

Our analysis highlights that among the prevalent drug shortages in Bulgaria for 2023, only two medicines – tafamidis and remdesivir – can be classified as innovative. Tafamidis is recognized for its novel approach to treating transthyretin-mediated amyloidosis, while remdesivir was repurposed for COVID-19 treatment after initial development for Ebola, marking significant advancements in therapeutic options. Notably, both medicines were included in Bulgaria's Positive Drug List (PDL) at the end of 2024 and will become part of the country's standard supply chain. Conversely, most of the medicines experiencing shortages, including well-established ones such as fentanyl, phytomenadione, sodium chloride, atracurium, rocuronium bromide, and dexmedetomidine, are integral to various medical procedures but do not qualify as innovative. These shortages often stem from economic disincentives, as lower profit margins discourage manufacturers from prioritizing production for less profitable markets such as Bulgaria – particularly in resource-constrained settings (Németh et al. 2022). Furthermore, logistical complexities and pricing strategies compound these issues, disrupting the supply chain of basic yet critical compounds such as sodium chloride, as well as more complex formulations like normal human immunoglobulins for intravascular administration. The disparities in drug availability are further influenced by the EU's pricing and reimbursement policies, which may render certain drugs such as cyclosporine and dacarbazine unprofitable in regulated markets, prompting suppliers to focus on more lucrative regions.

In the context of newer or orphan drugs such as remdesivir and tafamidis, limited manufacturing capacities and strategic market prioritization based on established reimbursement frameworks can intensify these challenges, underscoring the multifaceted nature of drug shortages that affect both innovative and non-innovative drug categories. This situation calls for a multifaceted strategy encompassing improved regulatory frameworks, incentives for manufacturing less profitable medicines, and enhanced logistical solutions to ensure equitable drug distribution across all markets.

Bulgaria, like many Eastern European countries, allocates a relatively small percentage of its GDP to healthcare,

which may contribute to its limited commercial attractiveness as a pharmaceutical market (European Observatory on Health Systems and Policies and Organisation for Economic Co-operation and Development 2023). Beyond external factors such as manufacturing and quality issues, commercial considerations and policy settings also likely play significant roles in exacerbating drug shortages. While national legislation includes mechanisms to ensure Bulgarian patients' access to essential medicines, these medicines are not consistently integrated into the standard supply chain, as reflected in recent stakeholder policy recommendations (EFPIA 2024). Without reliable predictions of hospital demand, quantities listed under Article 266a may be insufficient. The fact that 50% of the top 20 imported medicinal products in 2023 are included in the WHO EML highlights the need for national-level mitigation strategies to address these shortages effectively.

Various strategies exist across European countries to address the issue of shortages, including regulatory initiatives such as special permits, language exemptions, multi-stakeholder collaborations, and medicine supply reserves (Medicines for Europe 2024). There is a pressing need for a national strategic plan in Bulgaria to address these challenges effectively, drawing upon best practices observed in other EU countries.

The limitations of the current study stem from its focus on reviewing unavailable medicines imported into hospital settings through legislative mechanisms rather than conducting a comprehensive analysis of shortages at the national level, mainly due to a lack of such information. Additionally, another limitation is the study's narrow timeframe, which spans only one year.

Conclusion

Medicine shortages in Bulgaria are addressed through legislative mechanisms that facilitate access to essential medicines not readily available domestically. However, the effectiveness of these measures depends on improving demand forecasting and integrating these medicines into standard supply chains. This study demonstrates the significant reliance on imported medicinal products in Bulgaria, many of which are essential medicines listed in the WHO EML. These findings highlight the pressing need for targeted national strategies to address shortages effectively. Future research should expand to include a comprehensive assessment of medicine shortages at the national level. Such analysis will provide deeper insights into broader implications and help refine strategies aimed at strengthening healthcare resilience against ongoing challenges in medicine availability.

Additional information

Conflict of interest

The authors have declared that no competing interests exist.

Ethical statements

The authors declared that no clinical trials were used in the present study.

The authors declared that no experiments on humans or human tissues were performed for the present study.

The authors declared that no informed consent was obtained from the humans, donors or donors' representatives participating in the study.

The authors declared that no experiments on animals were performed for the present study.

The authors declared that no commercially available immortalised human and animal cell lines were used in the present study.

Use of AI

No use of AI was reported.

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Author contributions

P.M. conducted the regulatory analysis, analyzed current trends in drug shortages, interpreted the results from the medicinal product deliveries data, created the tables and followed up with a thorough discussion. J.A. extracted the results from the medicinal product deliveries data and created the corresponding figures. G.P. reviewed the manuscript, provided feedback and suggested improvements, which were incorporated. All authors have read and approved the final manuscript.

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Data availability

All of the data that support the findings of this study are available in the main text.

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