

Digitalization of health care and aspects of implementing electronic prescriptions in Bulgaria

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Abstract

The digitization of health systems is a topic of immense significance for the modern world. It holds the potential to transform the delivery of healthcare services, enhancing their quality, efficiency, and accessibility. Electronic prescriptions are a key element of this process, but it is crucial to ensure their implementation protects patients' personal data and privacy. This article examines the digitization of health systems in Bulgaria, with a focus on electronic prescriptions. It highlights aspects of data protection, the potential risks associated with data misuse, and the advantages of electronic prescriptions.

Keywords

electronic prescription, digitalization, health systems, personal data, European health data space

Introduction

Over the past five years, digital technologies have transformed the economy and society, impacting all sectors and the daily lives of all European citizens. Data is at the heart of this transformation, and even greater changes are expected in the future. Data-driven innovations will bring enormous benefits to citizens in the healthcare sector, such as improved personalized medicine, telemedicine, electronic health records, electronic prescriptions, referrals, etc. (Directorate-General for Health and Food Safety, European Commission 2022). In a society where

individuals generate increasing amounts of data, the way data is collected and used must prioritize the interests of individuals in accordance with European values, fundamental rights, and rules. This way, citizens will trust these types of innovations, especially in healthcare (Dipak et al. 2016; Team Zorg Enablers 2021).

The COVID-19 pandemic accelerated the digitalization of healthcare, leading to significant advancements and changes in how healthcare is delivered. The pandemic demonstrated that healthcare can be digitalized, with digital resources becoming the entry point to the health system. This requires a fundamental redesign of care processes,

focusing on the end-user, and creating a multifaceted and future-oriented organization (Team Zorg Enablers 2021).

On the other hand, this has led to the widespread adoption of digital health tools, including telemedicine, mobile health, electronic medical records, and artificial intelligence (AI). These technologies introduced into medicine are used for various purposes, such as patient monitoring, diagnostics, adherence to treatment, and data management. The large amounts of data generated by these digital tools have the potential to guide more precise and personalized care and accelerate the development and approval of medicines. However, ensuring data quality, privacy, and security are crucial considerations (Yuan and Li 2019; Getachew et al. 2023).

The aim of this study is to trace the digitalization of healthcare in Europe and Bulgaria and the impact of this transformation on healthcare systems concerning the regulation and success of electronic prescriptions and electronic health records.

Materials and methods

A systematic review method was used to review European and national regulations on the digitalization of health systems, as well as the associated introduction of prescribing and dispensing medicinal products through electronic prescriptions. The aspects of personal data protection and the potential risks associated with their misuse were analyzed, as well as the benefits of electronic prescriptions. The dynamics of prescribed and dispensed electronic prescriptions by type of recipe in Bulgaria during the first half of 2024 were reflected.

Results and discussion

The European dimension of connectivity in the prescription and dispensation of electronic prescriptions

The digitalization and connectivity of the healthcare systems of EU member states are progressing too slowly to jointly improve the quality, efficiency, and accessibility of healthcare services. Digital health has long been viewed as a facilitator for transitioning to evidence-based, patient-centered, and prevention-focused healthcare. However, the introduction of technologies such as electronic patient records (EPR), remote care, mobile health applications, and artificial intelligence (AI) has proven to be more challenging than anticipated, primarily due to data interoperability issues and the complexity of healthcare systems (Olesch 2022; Orăștean et al. 2022).

The equality of healthcare systems is crucial for building the future European Health Union. It is necessary to ensure that every European citizen can obtain prescribed medicinal products through electronic prescriptions, regardless of their location within the European Union, and to be assured that their health data will not be

misused. With this objective, the European Commission proposed the creation of the European Health Data Space, subsequently reaching an agreement in the European Parliament on a proposal for a Regulation of the European Parliament and the Council on the European Health Data Space (European Commission 2022).

The proposal aims to improve individuals' access to and control over their personal electronic health data (primary use of data), both at the national level and at the EU level, and to facilitate the use of data for research, innovation, regulatory purposes, and public policy goals across the EU (so-called secondary use of data). Additionally, it aims to enhance the functioning of the single market, particularly for the development, marketing, and use of digital health services and products (e.g., electronic health record systems (EHRs)). To this end, the proposal provides for a health-specific data environment, including common rules, infrastructure, and a governance framework. (European Commission 2023)

The proposal seeks to harmonize data flows to help individuals benefit from the protection and free movement of electronic health data, especially personal data. On the other hand, the proposal does not intend to regulate how healthcare is provided by member states, particularly concerning sensitive topics for member states such as telemedicine and online pharmacies, which remain within the competence of the EU member states.

A fundamental provision is Article 3, paragraph 1 of the proposed regulation, which states, "Individuals have the right to access their personal electronic health data, processed in the context of the primary use of electronic health data, immediately, free of charge, and in an easily readable, summarized, and accessible format." The proposed regulation stipulates that healthcare professionals will have access to the electronic health data of the individuals they treat, regardless of the member state of insurance and the member state of treatment. To ensure this connectivity, the European Commission will create a centralized platform for digital health, MyHealth@EU, which will provide services to support and facilitate the exchange of electronic health data between national contact points for digital health in the member states. Additionally, the regulation ensures that pharmacies operating in their territory, including online pharmacies, are enabled to dispense medicinal products based on electronic medical prescriptions issued by other member states. After dispensing medicinal products based on an electronic medical prescription from another member state, pharmacies report the dispensed medicines' data to the member state where the medical prescription was issued through MyHealth@EU (Julesz 2023).

Despite significant progress in the use of personal electronic health data for primary purposes in several member states, the process of cross-border healthcare remains slow. The MyHealth@EU platform has been implemented in only 10 member states and currently supports only two services (electronic medical prescription and patient summary). It is expected that by 2025, most member states

will have implemented the MyHealth@EU platform. Only after the platform is implemented by more member states and they develop the necessary tools will the use, development, and maintenance of these tools become more efficient across the EU (Bruthans and Jiráková 2023).

The implementation of electronic prescriptions in Bulgaria

In the national development program of the Republic of Bulgaria 2030, significant emphasis is placed on the development of e-health, making it a primary focus of healthcare policy (Council of Ministers 2020). Targeted efforts in this area contribute to improving access to and quality of healthcare services, transparency in financial management, reducing patient service time, enhancing the quality of healthcare services, and activities related to organization, control, planning, and forecasting within the healthcare system (Odone et al. 2019).

The measures outlined in the National Development Program of Bulgaria 2030 for the digitization of the healthcare sector include the creation of the National Health Information System (NHIS) using modern technological solutions focused on preventing chronic and non-communicable diseases to ensure effective and efficient care and achieve better health outcomes. The goal is to integrate all software applications related to human health.

Another measure in the national program is the development and implementation of telemedicine (especially for patients in hard-to-reach and remote areas, as well as patients with specific needs—chronically ill patients, elderly people, etc.) and the introduction of innovative applications for mobile health monitoring services. Telemedicine services will include online consultations to clarify diagnoses and discuss patient conditions based on diagnostic test results, remote medical activities, and more. The ultimate goal is to improve access to quality healthcare services for the population (Council of Ministers 2020).

According to the regulatory framework, the NHIS was established by the Health Act and operates under Ordinance No. N-6 of December 21, 2022, regarding the functioning of the national health information system. The system is maintained by the Ministry of Health and aims to collect, process, and store information about the health status of the population as a whole and for each individual. NHIS includes data on electronic health records of all citizens, as well as information obtained from registers, databases, and systems maintained by the Ministry of Health, its secondary budget holders, healthcare facilities, the National Health Insurance Fund (NHIF), insurance companies, and others (Ministry of Health 2022). Since 2020, numerous modules and functionalities of NHIS have been developed and implemented, including:

- The health information portal (HIP) provides a single entry point for access to NHIS.
- A unified environment for the exchange of medical data.
- Electronic medical dossier (EMD), electronic health record (EHR), electronic prescription, and electronic referral.

The introduction of electronic prescriptions is part of the government's program (adopted by Council of Ministers Decision No. 506 of July 26, 2023) and the "Management Program of the Republic of Bulgaria for the period June 2023–December 2024" (Council of Ministers 2023). The electronic prescription as a component of NHIS was realized in Phase-2 of NHIS development and has been functioning since June 2021. It covers the prescription and dispensation of products with so-called "white" prescriptions (appendix 2 of Ordinance No. 4 of March 4, 2009, on the conditions and procedures for prescribing and dispensing medicinal products), as well as medicinal products partially or fully reimbursed by NHIF (mandatory for this type of prescription since then). As of June 2023, electronic prescriptions are mandatory for medicinal products with a special prescription and dispensing regime (so-called yellow and green prescriptions according to Appendix No. 2 to Art. 3, item 2, and Appendix No. 3 to Art. 3, item 3 (Ministry of Health 2009, 2011).

A primary motive for the digitalization of medical prescriptions is that therapy prescribed on a paper prescription is not recorded in the patient's health dossier, making it impossible to retrospectively track, which compromises the therapeutic process and, in the case of antibiotics, contributes to antibiotic resistance alongside their widespread use.

Electronic prescriptions in Bulgaria were introduced in mid-2021, initially mandatory for medicinal products fully or partially reimbursed by the NHIF. In June 2023, the fully electronic prescription of medicinal products dispensed with yellow or green prescriptions was introduced. In October 2023, it became mandatory for anti-diabetic medications and systemic anti-infective medicinal products to be prescribed only via electronic prescription. The main reasons for mandating electronic prescriptions for these two groups of medicinal products—antibiotics and anti-diabetic medications—are to prevent shortages of these drug groups in the country, address antimicrobial resistance, and promote rational drug use. According to a literature review conducted in 2023 by Lebanova et al., the most common cause of antibiotic resistance is the irrational use of antibiotics (Lebanova et al. 2023). Data indicates an increasing trend in the use of anti-infective medicinal products in Bulgaria in recent years, necessitating conditions for rationalizing the use of this type of medication (Vankova et al. 2023).

The dispensing of these two groups of medications solely with e-prescriptions ensures transparency throughout the process, control over frequency and misuse without medical prescription, and effective tracking of the stock of medicinal products from these two therapeutic groups (Majcherek et al. 2024). These changes also comply with a decision adopted at the Health Committee meeting held on August 7, 2023, stating: "The Minister of Health should prepare the necessary amendments and additions

Prescribed and dispensed e-prescriptions by quarter

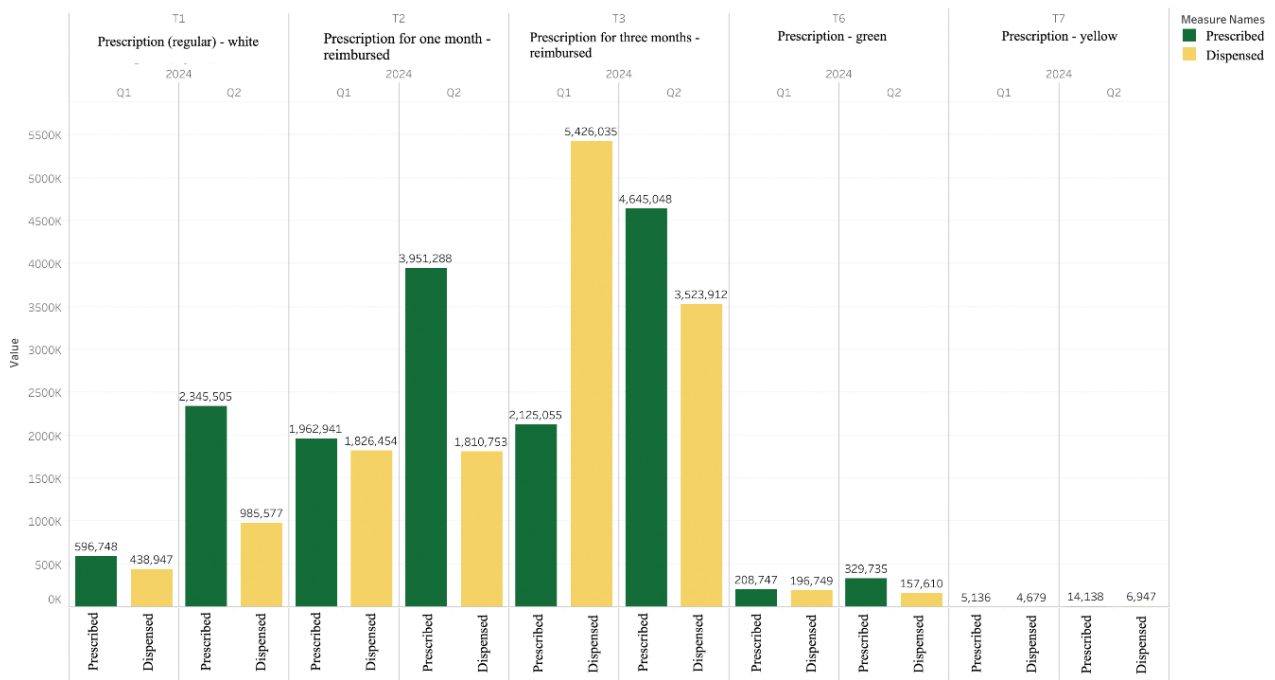


Figure 1. Dynamics of prescribed e-prescriptions, by type of prescription, in the first two quarters of 2024.

to Ordinance No. 4 of 2009 on the conditions and procedures for prescribing and dispensing medicinal products as soon as possible to expand the scope of medicinal products that are prescribed and dispensed with an electronic prescription” (Committee on Health 2023).

Furthermore, the introduction of electronic prescriptions significantly facilitates the dispensing of medicinal products in pharmacies by reducing the risk of misreading prescriptions (Ditya and Adisasmito 2019).

Since early March 2023, all medical professionals can issue electronic prescriptions anytime and from any location via the dedicated eRx mobile application. The issued prescription immediately appears in the patient’s electronic health dossier and can be filled out by any pharmacy. The app aims to assist doctors, dentists, and veterinarians in issuing electronic prescriptions when they do not have access to a computer with medical software. Thanks to this, during home visits or other emergencies outside the doctor’s office, an electronic prescription can be issued, complying with good medical practices, applicable laws, and NHIS requirements (Ministry of Health 2023).

According to a study published in 2022 during the Varna Medical Forum, Alexandrova et al. concluded that pharmacists feel confident when working with electronic prescriptions (Alexandrova et al. 2022).

To illustrate the widespread use of electronic prescriptions in Bulgaria, the following graph reflects the dynamics of prescribed and dispensed electronic prescriptions by type:

1. Ordinary (white) prescription;
2. One-month prescription reimbursed by NHIF;
3. Three-month prescription reimbursed by NHIF;
4. Green electronic prescription;
5. Yellow electronic prescription.

Regarding electronic prescriptions on the so-called “white” prescription forms, there is a significant increase in the issued and dispensed electronic prescriptions in the second quarter of 2024 compared to the first quarter of 2024. It is important to note that since the beginning of April 2024, all medicinal products falling within the pharmacological groups “medicinal products for the treatment of diabetes” and “antibacterial medicinal products for systemic use” according to the anatomical therapeutic chemical (ATC) classification of the World Health Organization (WHO) are required to be prescribed only by electronic prescription. The number of issued and fulfilled electronic prescriptions for medicinal products dispensed on yellow and green electronic forms remains relatively constant.

In Fig. 2, it is noticeable that electronic prescriptions are widely used across all age groups. The highest number of issued electronic prescriptions is for patients aged 70–74 years, followed by those aged 65–69 years. Additionally, during the first six months of 2024, there will be a significant number of electronic prescriptions issued for patients aged 0–9 years. This is largely due to the mandatory requirement that antibiotic prescriptions be issued exclusively electronically.

In Fig. 3, it is evident that nearly 16 million electronic prescriptions were issued in the first six months of 2024. A significant portion of these prescriptions are funded by the National Health Insurance Fund, meaning they are partially or fully reimbursed by the NHIF. About one-quarter of the issued electronic prescriptions are in the so-called “white” prescription form.

From a pharmacovigilance perspective, the extensive patient information available, including prescribed medications, dosages, and observed adverse drug reactions (ADRs) in electronic health records, can be analyzed

Patients with at least one prescribed e-prescription, sorted by age

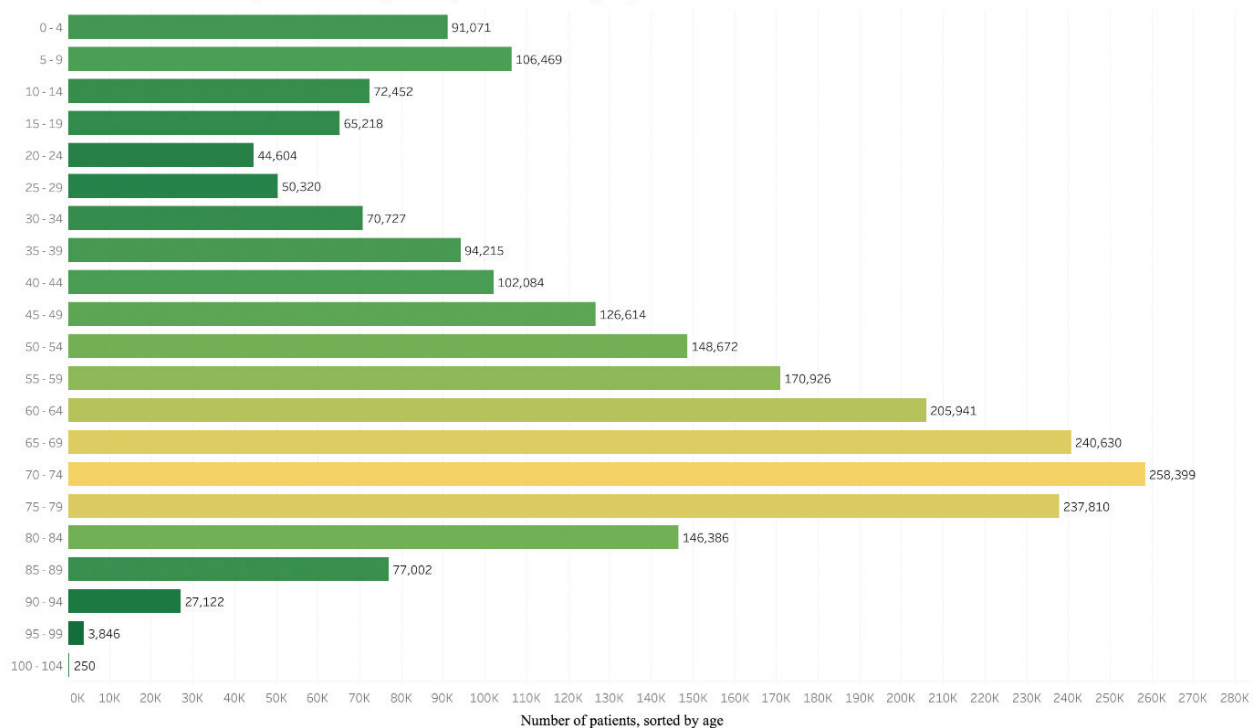


Figure 2. Patients with at least one e-prescription issued, by age group, in the last 6 months.

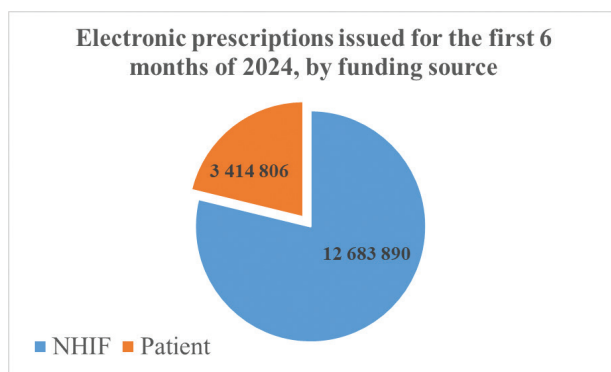


Figure 3. Electronic prescriptions issued for the first 6 months of 2024.

automatically using machine learning and artificial intelligence algorithms to detect potential ADRs more quickly and effectively than traditional methods (Coste et al. 2022). Additionally, electronic health records allow healthcare professionals quick access to the patient's complete medical history, which includes information on previous ADRs and medications used, crucial for preventing

repeated adverse reactions and optimizing therapy (Davis et al. 2023).

Conclusion

The digitalization of health systems is an inevitable process that holds the potential to transform the way healthcare services are delivered. Electronic prescriptions are a key element of this process, but it is essential to ensure their implementation protects patient privacy and data security. In Bulgaria, the digitalization of the healthcare system is underway, with electronic prescriptions being gradually introduced for different drug groups.

Despite the benefits, there are concerns about data privacy. Electronic prescriptions contain sensitive patient information, such as medical diagnoses and medications. It is crucial to ensure that this information is protected from unauthorized access and misuse.

There is a need to raise patient awareness of their rights regarding personal data. Healthcare institutions must invest in security technologies to protect patients' electronic data.

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