APPLICATION OF DIGITAL TECHNOLOGIES IN THE PHARMACEUTICAL SECTOR

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ABSTRACT

The introduction of digital technologies into the pharmaceutical sector is associated with the digital transformation and the shift in business models and production processes of the organizations that operate in the field. Digitalization provides an opportunity to develop and implement innovative technologies and medicines and their safety and efficacy monitoring. Various intelligent medical devices are used to collect and process data and allow different stakeholders (such as patients and health professionals) to exchange information, thus facilitating the process of therapy decision-making and therapy follow-up. Digital services improve patients' access to health information; they allow for improved therapeutic results and quality of life. In the pharmaceutical sector in Europe and America, digital technologies find application in the following areas: drug therapy management, pharmacogenomics, 3D printing of medicines, personalized digital pharmaceutical care, automatic dosing devices, drug reminder devices, and prevention of counterfeit medicines entering the legal supply chain. In Bulgaria, digital solutions are used to prevent the entry of counterfeit medicines via the introduction of a verification system; to create platforms and applications for health information and communication among patients, health professionals, and institutions, including through the introduction of e-prescriptions and e-referrals.

This paper aims to demonstrate the benefits of digitalization for the pharmaceutical practice in providing personalized pharmaceutical and health care, which leads to an increase in patient satisfaction and a reduction in healthcare costs.

Keywords: *verification, e-prescription, platforms and applications, pharmacogenomics, pharmaceutical care*

INTRODUCTION

One of the fastest-growing high-tech industries in the world is the pharmaceutical industry. Innovations in the field of drug delivery optimization provide effective drug therapy and reduced side effects. They are based on nanotechnology, innovative drug delivery systems, process automation and scaling of production facilities, digitalization, and artificial intelligence (1,2). New technologies and innovations enable companies working in the pharmaceutical sector to improve drug development and patient care (3,4). It is increasingly incorporating intelligent automation and control tools, advanced connectivity technologies, and highly efficient data collection and processing solutions (2). The various mobile applications and sensors make it possible to monitor the impact of therapy in the patient's daily life, to collect and analyze data related to the safety and efficacy of the medicinal product. The analysis of data from electronic medical records (such as diagnosis, results, history of drug therapy) and data on genomic, proteomic, and gene expression makes it possible to identify optimal therapies and predict how individual patients will respond to treatment (5). The digital age provides an opportunity for better information and involvement of patients in protecting and improving their health and improving their quality of life. Digital services facilitate the sharing of up-to-date patient health data between different stakeholders in the care process. This guarantees that the care provided is in line with the needs and preferences of patients (6).

AIM

This paper aims to demonstrate the benefits of digitalization for the pharmaceutical practice in pro-

viding personalized pharmaceutical and health care, which leads to an increase in patient satisfaction and a reduction in healthcare costs.

MATERIALS AND METHODS

We have used a documentary method and prospective analysis of publications in the 2003–2021 time interval focused on applying digital technologies in the pharmaceutical sector.

1. Entry of Digital Technologies in the Pharmaceutical Sector

The driving forces of the global pharmaceutical market today are, on one hand, innovation and, on the other hand, an aging population worldwide (7). Global healthcare is looking for solutions to reduce the ever-increasing cost of treatment, including through the introduction of digital innovations. Digital technologies are expected to help reduce long-term healthcare costs and achieve better therapeutic outcomes (8,9). Digitalization enables real-time communication between the patient and the healthcare system (including the pharmacist), and treatment decisions are based on real data (big data) and artificial intelligence (AI) (10).

The development of digital technologies allows the implementation of business analysis tools specifically developed for the pharmaceutical sector.

Digitalization in the pharmaceutical sector determines the changes in business models and processes in pharmaceutical companies and communication with consumers (11–16). In this sense, thanks to the advancement of technology in the pharmaceutical sector, there is an opportunity to develop and implement innovative technologies, new software solutions for the pharmaceutical industry, personalized care, online trade of over-the-counter (OTC) products and food supplements, and others.

Recent trends in digital transformation provide patients and pharmaceutical organizations with timely access to information related to the impact of a drug therapy or a drug product and how they affect their overall well-being in everyday life (6).

Online information platforms and communities enable patients and their families to discuss the progress of treatment, and some mobile applications can track the impact of treatment on the patient. In this way, healthcare professionals receive helpful information about the safety and efficacy of the medicine or therapy (5).

2. Examples of Application of Digital Technologies in the Pharmaceutical Sector in Europe and America

Digital technologies in the pharmaceutical sector in Europe and America are used in some of the following areas: management of drug therapy; pharmacogenomics; 3D printing of medicinal products; digital personalized pharmaceutical care; automatic dosing devices; medication reminder devices.

Pharmacogenomics

The term pharmacogenomics began being used in the scientific literature in the 1990s (17). Pharmacogenomics studies the variability in drug response due to heredity, and its implementation aims to reduce the morbidity and mortality caused by drugs. Pharmacogenomics is currently used to manage drug therapy (Fig.1). In this regard, pharmacists play a role in interpreting genetic information and the patient's response after the administration of a medicinal product to optimize drug therapy. Pharmacists compare patient-specific treatments based on genetic markers; predict patients' response to treatment; dose medicinal products based on the results of genetic tests; predict which patients will experience adverse reactions to selected therapies, and make informed recommendations to physicians for the best treatment for the particular patient that maximizes effectiveness while minimizing risk. Pharmacogenomics is the basis of the so-called "personalized therapy" (5,18-20).

Under Horizon 2020, a new personalized medicine model based on pharmacogenomics has been launched in Europe (U-PGx). It combines scientific and clinical expertise in pharmacogenomics to apply a preventive pharmacogenomic approach in clinical practice to demonstrate the benefits of clinical outcomes and quality of life for patients with savings for the health system. The project aims to lay the foundations for a future European health system in which

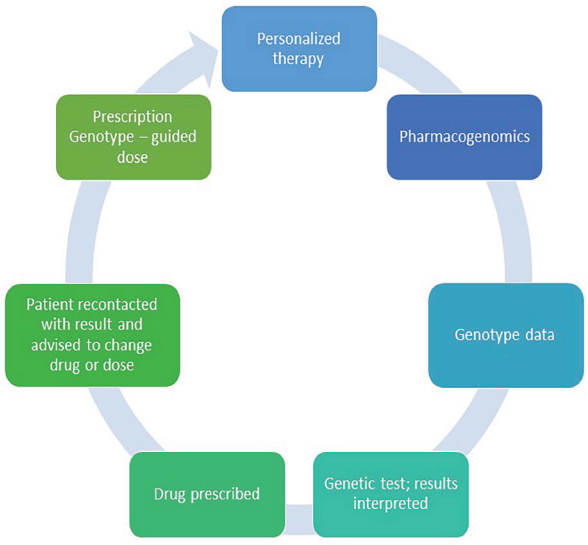

Fig. 1. Pharmacogenomics–personalized therapy (Adapted from: Adams J. Pharmacogenomics and personalized medicine. Nature Education. 2008;1(1):194. (19))

"effective and optimized treatment will be available to every European citizen" (21).

3D-Printed Drugs/Medical Products

The three-dimensional printing of medicinal products is an innovation related to pharmacogenomics (21,22). It is based on a unique patented process for creating a wide range of products that are characterized by rapid drug release, which is a guarantee for higher bioavailability; a wide range of options to improve the taste; and delivery of single doses for accurate and convenient application (21). 3D printers determine specific doses as well as drug forms for each patient. In addition, it is possible to combine several drugs in case the patient is diagnosed with more than one chronic disease and thus limit the unnecessary intake of more drugs (15). The US FDA approved the first 3D-printed pill in 2016 (23).

Medication Therapy Management (MTM)

MTM is an online platform for managing patient drug therapy in the United States, aimed at providing digital pharmaceutical care (24). The pharmacist reviews all medicines prescribed to the patient by all physicians, along with OTC ones, herbs, and supplements taken by the patient to identify and address drug-related problems (16). Problems may include improper use of medicines, duplication/unnecessary medications, and the need for medications for an untreated or improperly managed condition. Then the pharmacist provides training, consultancy, and advice to the patient or their caregiver to ensure proper implementation of the therapy (Fig. 2) (16,24-26).

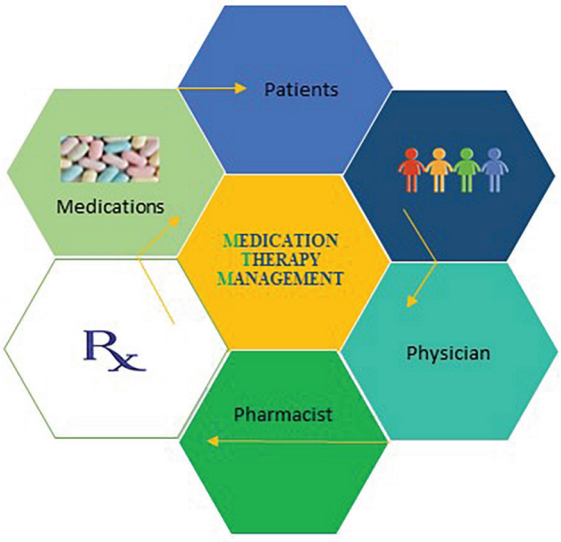

Fig. 2. Components of medication therapy management (Adapted from: Bluml BM. Definition of medication therapy management: development of profession wide consensus. J Am Pharm Assoc. 2005;45:566-72. (26))

Crucial to the pharmaceutical practice is the application of digital solutions to provide personalized pharmaceutical care. Here are some examples:

- **Video surveillance of the drug action based on nanotechnology**

The health and IT sectors are working on new technology for video surveillance of the action of drugs in the human body. Through special nanoparticles incorporated in the dosage form, it is possible to observe how the drug acts in the patient's body (27).

In 2017, the US Federal Drug Agency (FDA) had approved the world's first digital medicine: a pill with a built-in sensor. The sensor begins to transmit medical data after ingestion of the drug. The aim is to monitor adherence to therapy. The main concerns related to the "digital pill" are privacy—who receives the data and what it is used for (18).

- **Sensors and digital services for personalized treatment 24/7**

Personalized care in pharmacy can be realized mainly through sensors and digital services to provide round-the-clock care. Similar services are provided in the United States and some European countries. In the next few years, medicines manufactured by various pharmaceutical companies are expected to be a part of a digital ecosystem that constantly monitors the patient's condition and provides feedback to the caregivers involved (multidisciplinary team). This ecosystem will help improve health outcomes by adapting therapy to clinical outcomes and patient needs and will allow remote monitoring by healthcare professionals of the patient's condition and adherence to therapy (16,28). Numerous wireless sensors are currently available on the market to measure a patient's biophysical performance. The benefits of digital personalized care applications are related to improved health outcomes, adherence to therapy, cost avoidance, and delays associated with specialist visits (5,29).

- **Automated dispensing units/cabinet (ADC)**

The automated dispensing cabinet (ADC) is a decentralized drug distribution system that provides computer-controlled storage, dosing, and tracking drugs to patients in the ward or pharmacy (Fig. 2). It is used in various countries in Europe and America (29). Thus, human errors are reduced, and the emphasis is on staff contact with the patient instead of paperwork (3). If ADCs are associated with barcode process automation technology, an electronic match between the prescribed and the selected drug is provided (17).

- **Medication reminder devices—smart dispenser**

Many different devices on the pharmaceutical market provide reminders to patients to take medications through the related smartphone and app. The application introduces information on the number of dosage units and the time of their dosing. The device, which easily fits in the palm, stores the dosing mode and releases the tablets at the touch of a button. If necessary, it can send various optical and even acoustic signals. Consumers should be reminded to take their medication until the appropriate dose has been dispensed. Patient compliance can be accounted for through developed applications (25). If the patient fails to take his (correct) dose from the smartphone, a text message or email is sent to the caregiver or family member. The dispenser locks itself after the correct number of pills has been dispensed until the following medication. This prevents incorrect dosing (4,30).

European Medicines Verification System (EMVS)

The European Medicines Verification System (EMVS) aims to improve patient safety by obliging marketing authorization holders and manufacturers to put in place a system to prevent falsified medicines from entering the legal supply chain. EMVS reliably and consistently supports the legal requirements imposed on all European pharmacists and wholesalers to verify each package of prescription medicines (31). The EMVS must keep the logbook data for extended periods (up to ten years) for regulatory, supervisory, and reporting purposes (31). The EMVS consists of a central European center that processes data on products, batches, and packaging uploaded by drug manufacturers and parallel distributors (companies that support the distribution of pharmaceutical products across national borders). The European center disseminates this data in the national systems for each market in which the product is authorized. The marketing authorization is granted at the national level, and each country has its national system (Fig. 3) (32,33).

3. Application of Digital Technologies in the Pharmaceutical Sector in Bulgaria

Many experts in Bulgaria believe that the pharmaceutical sector should rely on digitalization for its development (8,10,15,33). Although it is on the path of digitalization, the pharmaceutical industry in Bulgaria is currently lagging behind the leading countries in Europe and the United States. Different activities and services have been digitized (drug verification system, platforms for digital communication and information, etc.), and local registers and databases have been set up (34). Here are some examples of digital solutions in Bulgaria:

- **National Medicines Verification System**

To prevent the entry and spread of counterfeit medicines and to ensure the supply of patients with authentic medicines in Bulgaria, a National Medicines Verification System has been established, which is linked to a central European hub. It exchanges data on manufactured drug packaging to remove counterfeit drugs from legal supply chains. Serialization of Rx drugs is performed at the manufacturer and verification at the pharmacy (31,33). The scope of the Verification System is for prescription-only medicinal products, except Annex I products and in addi-

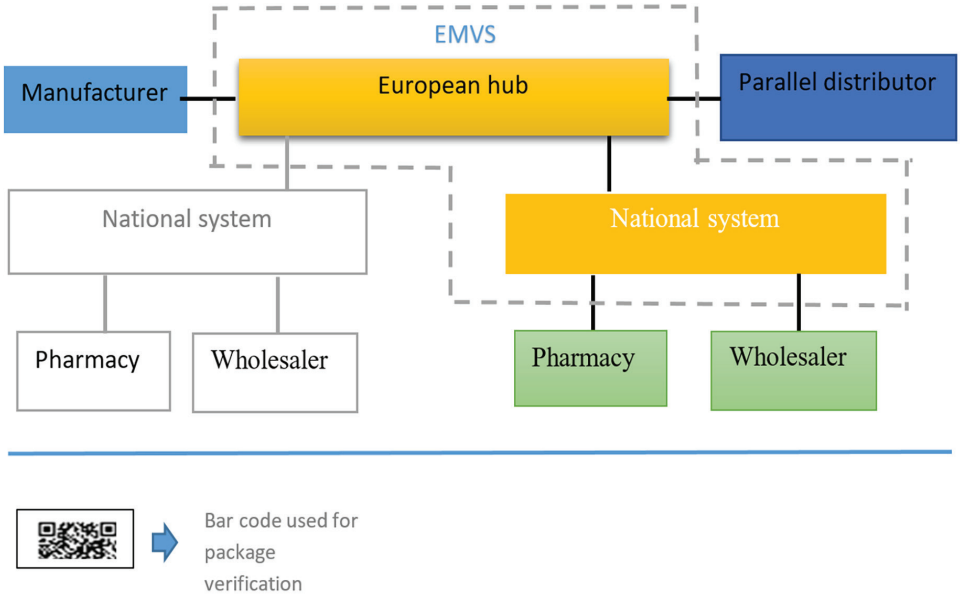

Fig. 3. Components of the European Verification System (Source: Paunova I. Verification of medicines—digital innovation for patient safety. PPT, 27.11.2020 (33)).

tion Annex II products (omeprazole) of the Delegated Regulation. Verification of a specific medicinal product is achieved by scanning the GS1 Data Matrix code (9), which marks the individual drug packages. Serialization of Rx drugs is performed at the manufacturer and verification—at the pharmacy (Fig. 4) (9,33).

The verification system conditions a very high level of security provided that the products are delivered to the legal supply chain under EU-FMD. All drugs, including COVID-19 vaccines, need to be serialized and have an anti-counterfeiting agent (9,33).

- **SAT Health**

SAT Health is a reliable pharmaceutical information and technology provider that operates on the Bulgarian market and provides reliable world data and analyzes, specialized market health research, evidence-based consultation, technological solutions for the healthcare industry, and patient support programs (10).

- **Bulgarian Cluster for Digital Solutions and Innovations in Healthcare**

Bulgarian Cluster for Digital Solutions and Innovations in Healthcare, operating since November 2019. It is a non-profit association supporting innovative companies and organizations in digital solutions in healthcare to build a digital health ecosystem and establish a sustainable and efficient health environment for patients, medical professionals, society, and institutions (35,36).

An online platform functioning as a medical consultant for symptom analysis and research is developed by framar.bg. It aims to facilitate the verification of long medical leaflets and also provides a symptom-checking application and diagnostic modules with a specific medical focus (37).

CONCLUSION

The application of digital technologies in the pharmaceutical sector in some European countries and the United States aims to improve the quality of pharmaceutical care, health outcomes, prevent the entry of counterfeit drugs into the legal supply chain, and facilitate communication between pharmacists, doctors, and patients. Digitalization is conducted in two directions in Bulgaria: preventing counterfeit medicines and digital solutions for improving the health environment for patients, health professionals, and institutions. The penetration of digital technologies in the pharmaceutical sector is of great importance for meeting the needs of society by applying the latest developments in the technology sector and sharing good practices.

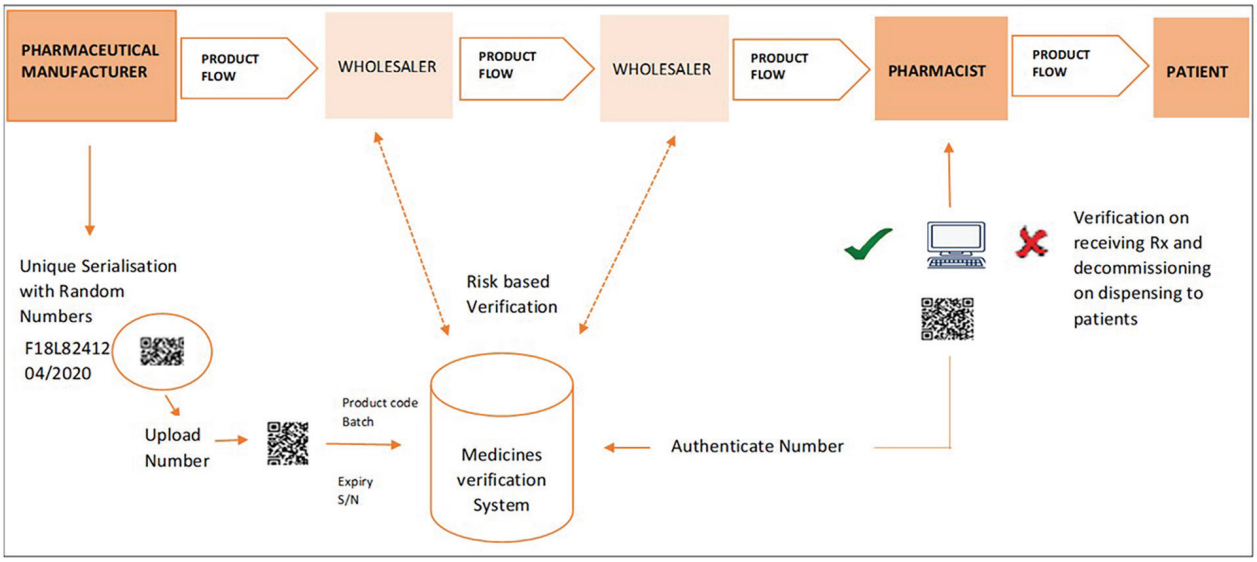

Fig. 4. Serialization of Rx drugs at the manufacturer and verification at the pharmacy (Adapted from: Paunova I. Verification of medicines—digital innovation for patient safety. PPT, 27.11.2020 (33)).

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