



Position Paper on Big Data & Artificial Intelligence in Healthcare

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 31 European countries. In Europe over 400.000 community pharmacists provide services throughout a network of more than 160.000 pharmacies, to an estimated 46 million European citizens daily.

PGEU's objective is to promote the role of pharmacists as key players in healthcare systems throughout Europe and to ensure that the views of the pharmacy profession are taken into account in the EU decision-making process.

1. Introduction

The shift towards the digital economy has accelerated the pace at which new technologies are transforming the healthcare sector. Health systems in Europe are awash with data, whose range and volume are growing exponentially. Increasingly generated data is opening up possibilities for the use of technologies such as Artificial Intelligence (AI) and blockchains which are poised to disrupt healthcare on a global scale.

Community pharmacy acknowledges the value Big Data and AI can have for European health systems and is ready to ensure that the use of new, innovative and automated technologies is **always accompanied by expert and professional advice**, such that their potential can be fully utilized **to deliver more efficient, sustainable and high-quality healthcare services** to the patients, supporting and complementing the face-to-face interaction between healthcare providers and patients.

In order to accomplish this, European community pharmacists are committed to:

1. **Build on their fully computerized systems and on innovative technologies** to improve workflow efficiency while promoting patient safety, therapy effectiveness and offering the highest standard of pharmacy services to its patients.
2. **Remain a trusted source of reliable and independent health information** for patients in the era of digitalization and of multiplication of information sources, by making the innovative digital solutions integral to community pharmacy practice.
3. **Play a pivotal role in the design, development, testing, implementation and uptake of ICT innovations** to ensure they are fit for practice.
4. Continue to **provide advanced pharmacy services and promote remote monitoring and care, read-write access to shared electronic health records, use of electronic prescription and secure analysis of big data** repositories, registries and other pharmacy-held databases.
5. Use their unique position at the heart of European communities and **leverage the potential of Big Data and AI** to provide more **personalized advice to patients** and **robust, evidence-based information** on issues related to their therapies while **promoting safe and rational medicines use**.

This paper is aimed to show how community pharmacists are equipped to address the challenges and opportunities arising from digitalization in healthcare. It also provides key policy recommendations to take full benefit of the potential of Big Data and AI in healthcare and promote sustainable and resilient health systems in Europe.

2. Big Data and AI in Healthcare explained

Big Data is generated today through a plurality of sources and is defined in various ways. In healthcare, Big Data refers to large routinely or automatically collected data, which is electronically stored. This data can be reused and comprise links among existing databases to improve health system performance.¹

The possibility to merge and connect existing databases is envisaged by the European Commission strategy to boost healthcare data sharing in the EU². PGEU welcomes the Commission's strategy: community pharmacists want to secure patients access to health data and – subject to each patient's consent – promote the sharing of their data across borders to enable more personalised diagnoses and medical treatments.

Within the Digital Single Market strategy, the European Commission has put forward a proposal for a European approach to boost investment and set ethical guidelines in Artificial Intelligence (AI)³, encouraging uptake of these technologies by public and private sectors. The European Commission intends to use the potential of new technologies to improve healthcare and medical research, by setting out a plan to secure citizens' healthcare while fostering European cooperation and health data sharing.

The implementation of eHealth, mHealth, telemedicine is linked to the collection, analysis and the speed in the application of Big Data in health. ⁴ The remarkable amount of data in health contributed so far to the widespread adoption of electronic health records and e-prescribing systems, with community pharmacists being at the forefront of these developments in several European countries. As it turns out from daily practice, more and more patients ask pharmacists to provide advice on how to interpret health (medicine) information they acquire from other sources, such as the media, the internet or mobile apps. This involves the interpretation by pharmacists of health data generated through wearable devices and digital point-of-care tests in community pharmacies, which have an enormous capability in early detection of undiagnosed chronic disease and potential adverse events and in monitoring of adherence and effectiveness of therapies.

Along with increasing availability of Big Data, there have been advancements in **AI techniques** that enable machines and computers to sense and act, either on their own or to augment human activities. In healthcare, as in other sectors, AI has the potential to introduce new sources of growth, changing how

¹ Source: https://ec.europa.eu/health/sites/health/files/ehealth/docs/bigdata_report_en.pdf

² Source : http://europa.eu/rapid/press-release_IP-18-3364_en.htm

³ Source : http://europa.eu/rapid/press-release_IP-18-3362_en.htm

⁴ Big Data is often referred to as being characterized by four dimensions: Volume, Velocity, Variety and Veracity – the latter being a mix of variability and complexity - the so-called four's V of Big Data.

work is done and reinforcing the role of people to drive growth in the sector.⁵ AI and machine learning can potentially free health professionals from routine tasks and save lives through efficient early detection.

In the pharmacy sector, the widest use of AI is automated dispensing technology: in Europe between 30-40% of community pharmacies use this technology.⁶ This is applied in the pharmacy as automated pack dispensing robots, central filling systems and automated daily dosing systems. After deployment of this technology, pharmacists would see significant benefits in terms of safe dispensing and saved working time on dispensing which pharmacists can spend on providing patients with professional advice and services. The take-up of automation in community pharmacy is set to grow, with robots becoming smaller and more affordable.

The evolution of **automated dispensing technology** goes hand in hand with the growing implementation of clinical decision support systems in community pharmacy⁷. Clinical decision support systems interact with electronic health record systems by receiving the patient data and medicine characteristics as input and by providing alerts for potentially expected adverse reactions (e.g. medication interactions, allergies) and medication errors (e.g. overdosing). These are increasingly linked with algorithms in the form of clinical rules⁸ and take into account more and more relevant patient data and medicine characteristics (where these are available to the pharmacist) such as lab and pharmacogenetic test results⁹. These allow for rapid and comprehensive assessments of the patients' medication safety at the point of dispensing in the pharmacy.

Another type of AI technology with great potential in healthcare is blockchain.¹⁰ At its core, blockchain is a technology to create immutable and distributable data and transaction records which can be shared peer to peer between networked database systems. Data stored in blockchain cannot be changed or recognized until it reaches the recipients – that is what makes blockchain a theoretically secure technology concerning data integrity.

Managing and securing data within healthcare and supply chain management are two clear examples of principal concepts influencing and being impacted by possible blockchain adoption. Blockchain's records can be used to provide health records for individuals, while giving all patients more control over their own information through verifiable consent.

⁵ Source: <https://www.accenture.com/us-en/insight-artificial-intelligence-future-growth>

⁶ Source : <https://www.pharmacymagazine.co.uk/the-robots-are-coming...>

⁷ PGEU Statement on eHealth Annex: eHealth Solutions in European Community Pharmacies

⁸ Helmons PJ, et al. J; Drug-drug interaction checking assisted by clinical decision support: a return on investment analysis; Am Med Inform Assoc 2015;22:764–772. doi:10.1093

⁹ <https://www.knmp.nl/downloads/poster-pharmacogenomics.pdf>

¹⁰ Source: <https://www2.deloitte.com/us/en/pages/public-sector/articles/blockchain-opportunities-for-health-care.html>

3. Big Data and AI to make European health systems more sustainable

European health systems are facing major challenges related to the sustainability and quality of healthcare provision, as a consequence of demographic change, population ageing and rising prevalence of chronic conditions. Public expenditure on health and long-term care has been increasing over the last decades, accounting for 8.5% of GDP in the EU and is expected to rise by an additional 2% to 4% of GDP by 2060.¹¹ EU Member States' capacity to provide high quality care to all will depend on whether health systems will manage to become more resilient and sustainable. To this end, the "State of Health in the EU"¹² recommended Member States to pursue the following policies: strengthening health promotion and prevention; investing in primary care systems and shifting healthcare out of the hospital sector towards more cost-effective primary and ambulatory care; as well as promoting integrated care.

In this context, innovative solutions that make use of digital technologies, including eHealth, Big Data, AI are seen by the European Commission as opportunities to transform healthcare systems.¹³ Big data and improved data analytics capabilities, as well as the use of clinical decision support systems by health professionals and use of mobile health tools for individuals to manage their own health and chronic conditions are just some of the possibilities offered by digitalization to achieve more sustainable healthcare¹⁴. To promote the use of eHealth, Big Data and AI in health systems, **PGEU believes that recommending, monitoring and advising patients on their conditions with mHealth and eHealth solutions should be a reimbursed service for community pharmacists**. Given the **excellent accessibility of the community pharmacist**, a healthcare professional at the heart of each community, and given the pharmacists' existing services (in pharmacovigilance, managing side effects, adverse reactions, interactions, dose adjustments, therapeutic recommendations, providing information to patients and public health promotion), the PGEU believes community pharmacists are **well placed to deliver such a funded service**.

Community pharmacists use eHealth tools and mHealth applications daily, when dispensing electronic prescriptions, checking for medication interactions, accessing electronic medications records or providing support for adherence via a mobile app. As such, they should be seen by European and national

¹¹ Source: https://ec.europa.eu/info/sites/info/files/file_import/ip037_vol1_en_2.pdf

¹² Source: OECD/EU (2016), Health at a Glance: Europe 2016 – State of Health in the EU Cycle, OECD Publishing, Paris. <http://dx.doi.org/10.1787/9789264265592-en>

¹³ Source: Health and care has been identified by most of the digital Public-Private Partnerships in Horizon 2020 as a core business area where digital technologies can play a major role. The Digitising European Industry (DEI) high level group recently established a working group on health.

¹⁴ Source : <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2017:440:0003:0009:EN:PDF>

policymakers as **key reference** in the **formulation of eHealth policies** and in **developing policies on Big Data & AI**.

4. What is next for Community Pharmacy?

The advent of digitalization, Big Data and AI to healthcare presents the pharmacy professions with challenges and opportunities which can be summarized as follows:

4.1. Challenges

The extent to which Big Data and AI will have a positive impact on improving accessibility of care, integration of primary care systems, health outcomes (e.g. in terms of medicine safety and therapy effectiveness) for the patients as well as on increasing cost effectiveness of health interventions, will depend on a number of factors.

These factors include, for instance, the **usability, quality and interoperability of data collected** as well as the **quantity of those data**. There is indeed one crucial prerequisite for the use and the development of AI-driven health technologies: the availability of a large amount of informative health data. The more the data, the higher is the level of intelligence which machine learning tools can produce. The **more relevant and informative the data**, the **more accurate AI predictions** will be.

In addition, it can be expected that the adoption of big data and related analytics technologies in healthcare will also raise some barriers and challenges concerning the use of sensitive information belonging to patients. To keep patients' trust in health systems unchanged, it will be essential that the collection of patient data and information will be done in compliance to GDPR (General Data Protection Regulation). As the closest and most accessible point of access to care in Europe, **community pharmacists are key to bridge patients and health systems** and **ensure patients are well informed on how their healthcare data is used to improve the safety and quality of their treatment**.

4.2. Opportunities

As the quality of pharmacy healthcare services continues to grow, there are **three main ways by which pharmacy can leverage the Big Data and AI** disruption in healthcare to shape healthcare outcomes:

1. Being the **most accessible and affordable point of access in health systems**, community pharmacists can use AI and new digital technologies to dedicate more working time to the provision of healthcare services and to direct patient care.
2. Big Data and AI in pharmacy, if adopted within interoperable information systems, can use patient data and clinical history to support the pharmacists in providing **more personalized healthcare services and expert advice**.
3. The potential of eHealth and mHealth tools can be used to **provide real-time capture of data** which can enable community pharmacists **to follow up with at-risk patients** on their conditions **and to monitor their progress** during therapy.

In addition, **pharmacists already have an early form of AI in place**: it is the **pharmacy software** which provides housing for data concerning **medication history** of the patient, **patient use of medication**, **clinical rules** (clinical decision support) and **adherence data**, gathered in compliance with GDPR. The next generation of pharmacy software using AI to implement a technology-based information expert system to identify timely adverse drug-reaction or medicines interaction problems based on patient data captured from the pharmacy system and other external data systems.

In this way, pharmacists would need to spend less working time on identifying serious drug-related problems. These time savings coupled with potential automation of dispensing process could **free a significant amount of time** for the pharmacists **to provide a broader range of patient-centered healthcare services**.

5. Conclusion

Pharmacists can contribute to the gathering of large amount of data in healthcare. They have been using electronic health records for almost 20 years to provide better patient care and monitor the patients' conditions. Informatic tools in pharmacies have been crucial as an information source for medicines and medical devices, use of e-prescription systems, repeat prescriptions systems, invoicing, follow-up services for patients, traceability and pharmacy services.

This variety of sources can generate Big Data which can be further analyzed, provided that they are compliant with the provisions of the GDPR. Big data analytics and AI may be useful tools to provide patients with better guidance on how to use their medication; to optimize value of data from m-health

technologies; to promote prevention and better everyday lifestyle guidance; to support patient monitoring and adherence as well as to obtain better health outcomes.

Community pharmacists have the infrastructure, culture and expertise to make use of the potential of Big Data and AI in healthcare. These technologies can increase the efficiency of processes within the pharmacy which in turn can facilitate added value service implementation. Therefore, community pharmacists acknowledge the benefits of appropriately integrated digital solutions to complement practice.

To fully take advantage of the potential of Big Data & AI in healthcare and promote sustainable and resilient health systems in Europe, this paper includes the following five recommendations:

1. **Involve community pharmacists** as experienced users of digital health tools **in the formulation of digital policies** at local, national and European level **as well as in the development of guidelines and methods on the sharing of Big data and deployment of AI** in healthcare.
2. **Reward with reimbursement community pharmacy services** involving recommending, monitoring and advising patients via mHealth and eHealth tools.
3. Facilitate the production of Big Data in healthcare, **via linking electronic health records with e-Prescribing systems**, allowing health professionals involved in patient care to **access the necessary patient's information**, subject to the patient's consent. **Promote interoperability of information systems** in Europe to foster exchange of data across community pharmacies.
4. **Enable community pharmacists to update electronic health records**, if needed, to identify and address potential medication and patient safety-related issues.
5. Harness the potential of AI in healthcare and use it to **promote more collaboration across many different health professionals** serving the same patients as well as to promote **integration of primary care systems**.

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