Position Paper on Digital Health

Pharmaceutical Group of the European Union

About Us

The Pharmaceutical Group of the European Union (PGEU) is the association representing community pharmacists in 32 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.

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Executive Summary

The development and expansion of digital health is expected to bring significant benefits to patient care and health systems performance[1] yet digital solutions as well as standards and certification processes of digital health products and services are fragmented at both national and European levels.

The care of sick and vulnerable people is a deeply human process based on trust and human closeness. PGEU is strongly convinced that digital technology, if implemented correctly, can be a very useful complementary tool to facilitate dialogue among health professionals and meet patients' healthcare needs. However, we do not lose sight of the importance of face-to-face relationships between community pharmacists and their patients. Technology therefore should be designed according to the goals of healthcare and not vice versa, and in such a way that it does not prevail over direct human contact, nor cause digital exclusion. As experimented by the pharmacy network at the heart of European communities, patients need and value true human relationships.

Community pharmacists across Europe commit to integrate innovative, beneficial Information and Communications Technology (ICT) and digital health solutions in practice, to complement the existing - and often generations-long – face-to-face patient-pharmacist relationships[2].

The use of digital health solutions, big data, Artificial Intelligence (AI) and automation can make pharmacy processes more efficient, making it easier to implement added-value services and allowing community pharmacies to follow up with at-risk patients and monitor their progress during therapy. This can also be seen with the evolution of electronic Health (eHealth) and mobile Health (mHealth) platforms, which assist both community pharmacists and patients alike for aspects such as counselling, medication adherence, pharmacovigilance and clinical risk management on medicine use (drug drug interactions, etc.), home delivery and booking appointments. Moreover, digital health solutions have a great potential to promote more collaboration across different healthcare professionals serving the same patients as well as to promote integration of primary care systems.

However, low levels of digital literacy and access to internet and digital tools can still be observed among a significant part of (vulnerable) subgroups of the European population, which requires healthcare systems to closely monitor risks of generating unintended equity gaps as a result of an increased integration of digital health solutions. In addition, other challenges and concerns related to rise of digital solutions in healthcare are to be closely monitored and effectively addressed, such as related to the commercialisation of healthcare and the possible abuse of (patients') health data.

In the light of these key developments in digitalisation, PGEU outlines in this paper its position on key aspects of digital health for the future, whilst providing an overview of the community pharmacy contribution in digital health across Europe.

A number of recommendations are made to policy makers which are centred around the following 5 main messages:

1. Advance the uptake of trustworthy digital health solutions in healthcare practice that bring meaningful benefits to patients and healthcare systems;

2. Support community pharmacists, as trusted sources of health information, to help progress the safe digitalisation of healthcare;

3. Exploit the potential of Big Data & AI in healthcare;

4. Develop trust in the use and re-use of data in healthcare by all stakeholders involved;

5. Safeguard consumer protection for the cross-border online provision of medicines and digital health services within the EU Single Market.

The Community Pharmacy Role in Digital Health

It is expected that the impact of digitalization on health, healthcare delivery and health systems, can and will likely be profound, according to the Opinion of the European Commission Expert Panel on Health[3]. In particular, health services have already undergone digital transformation which impacts healthcare delivery. The European Commission Companion Report[4] to the State of Health in the EU 2019 finds out that digital transformation of healthcare – and in particular of health promotion and disease prevention – is one of the 5 biggest trends in the National Health Systems (NHSs) of EU Member States.

The implementation of eHealth, mHealth, AI and automation in healthcare is linked to the collection, analysis and the speed in the application of data in health[5]. The remarkable amount of health data 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 (especially medicines) information they acquire from other sources, such as the media, 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 as well as in monitoring of adherence and effectiveness of therapies.

Moreover, community pharmacists have made significant proactive investments in information and communications technology (ICT) infrastructure over the past three decades. This makes pharmacists ideally placed to play a pivotal role in designing, developing, testing, implementing, evaluating, and ensuring the uptake of new ICT innovations and confirming they are fit for practice in community pharmacies. ICT creates the potential for remote monitoring and care, read-write access to shared medical records, electronic prescriptions, secure pharmacist advice in online services, secure analyses of big data repositories, registries and other pharmacy-held databases for epidemiological studies to improve health outcomes. It can also allow indications of the medicine on the electronic prescription and two-way e-communication between pharmacists and other healthcare professionals.

This multi-professional proactivity in digital health can thus result in high quality healthcare systems that fulfil the needs of all citizens. However, at all times it needs to be ensured that patients remain in control of their own health data and that they are able to decide to freely and independently about their treatment, the team of healthcare professionals involved in their care as well as their access points for treatments. This includes having the right to decide to which pharmacy their (e-)prescription goes, as pharmacies in some European countries have been observing worrying practices of health insurance companies directing e-Prescriptions to certain pharmacies where these insurances obtain a rebate. At all times it should therefore be ensured that the e-Prescription does not become a commercial commodity.

At the same time, it is known that the level of digital literacy (ability to use digital devices effectively) and skills among people in Europe still varies strongly across different subgroups and age categories of the population. A 2017 European Commission report

has revealed that 169 million Europeans between 16 and 74 years – 44% – do not have basic digital skills[6]. Moreover, a significant percentage of households in Europe still does not have guaranteed access to internet, with also strong differences that can be observed across different European regions and countries[7]. Especially in more rural areas, which are often populated by an older tier of the population, there is usually more limited access to digital solutions compared with city areas. People lower along social gradients tend to have higher disease burdens and health needs, yet they are more vulnerable regarding access to and understanding of health information[8]. They may be less aware of issues of privacy, health data use, and data protection and are also more likely to experience digital exclusion.

A key prerequisite for the increasing integration of digital health solutions in healthcare systems is therefore to safeguard equity for all patients and ensure that alternative solutions remain available for those patients who are not able to rely on digital solutions. Overall, technology should be used according to the goals of healthcare and not vice versa, and in such a way that it does not prevail over direct human contact, nor cause digital exclusion.

a. Electronic and Mobile health

Today, community pharmacists across Europe use eHealth tools on a daily basis, whether it is dispensing electronic prescriptions, checking for medication interactions when accessing electronic medication records (clinical risk management on medicine use), providing support for adherence via a mobile app or telephone call, acting as the patient's entry point into the health system, or for other uses.

One of the most important aspects of eHealth for community pharmacists is the use of the shared Electronic Health Record (EHR), which if implemented correctly, could bridge the information gap between healthcare professionals and patients. The EHR allows pharmacists to check for consistency and correctness of a patient's medication history, thus contributing to patient safety and minimizing medication errors[9].

A number of advantages can be achieved from using eHealth and mHealth solutions within the pharmacy network. They include greater accessibility to care, further integration of the primary healthcare system, improved health outcomes, reduced costs to health system payers, improved health literacy, support for self-care, enhanced patient safety and increased quality of care. The deployment of these tools is supported using best practices within pharmacists' regulatory and ethical frameworks, as well as by pharmacists keeping their ICT knowledge and skills up to date as required.

Evidence shows that shared computerised EHRs are effective in reducing a range of medication errors in primary care[10]. As EHRs are usually held by the patient's family physician, it is important that they are linked with the ePrescribing system and pharmacy-held patient medication records. When this is achieved, healthcare professionals involved in patient care (including pharmacists) can access necessary patient information to provide safe and effective care, not just prescription information[11]. There also should be a facility to update the EHR with relevant information when necessary, in order to increase the capacity to identify and address potential medication and patient safety-related issues.

In addition, trustworthy mHealth applications can also help patients to manage their health more actively and live more independently due to self-assessment and remote monitoring solutions[12]. Healthcare institutions and healthcare professionals face a continuous need to update and expand health facilities, technology and equipment, at great expense. In order to ensure the safe use of mHealth solutions for citizens assessing their health and wellbeing, healthcare professionals should be trained to advise patients in an unbiased way on the options available on the market (e.g. highlighting any certification schemes and regulation, and their significance)[13]. As mHealth services can be connected with a pharmacy service with the aim of improving public healthcare, community pharmacies should be reimbursed for the utilisation of mHealth and eHealth tools and for contributing to improved health outcomes for patients and reduced healthcare costs.
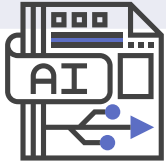
b. Big Data & Artificial Intelligence in Healthcare

PGEU acknowledges[14] the value of innovative technologies such as Artificial Intelligence (AI) as well as the access and analysis of Big Data. We consider these technologies to be a useful tool to support healthcare professionals and EU health systems. In routine practice at national level, these tools can bring a positive contribution by improving workflow efficiency, promoting patient safety and therapy effectiveness, and offering the highest standard of pharmacy services to patients. Still, we believe that AI shall always be accompanied by pharmacists' expert and professional advice.

In the era of digitalization and multiple information sources, community pharmacy remains a trusted source of reliable and independent health information for patients.

In order to harness the benefits of digital for enabling meaningful innovation and enhancing patient care, a key requirement is to develop trust by all stakeholders involved through guaranteeing a high level of data protection as well as ethical principles. Patient data must be processed under a high level of data protection standards within trustworthy infrastructures that enable access to secure data services. It also must be ensured that data access and analysis are in line with European rules for privacy and data protection.

In healthcare, as in other sectors, AI has the potential to introduce new sources of growth, changing how work is done and reinforcing the role of people to drive growth in the sector[5]. AI and machine learning can potentially free healthcare 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 pharmacy. 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 rules[15] 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 results[16]. These allow for rapid and comprehensive assessments of the patients' medication safety at the point of dispensing in the pharmacy.

PGEU supports a European approach to excellence and trust on Artificial Intelligence, as outlined in the White Paper on AI[17] published by the European Commission, with the twin objective of promoting the uptake of AI while addressing the risks associated with certain uses of this new technology in some sectors, including healthcare.

In addition, clear professionals standards and ethical principles as well as legally binding assessment criteria to ensure transparency of AI systems in healthcare are needed. Transparent, clinically and ethically validated AI and systematic quality checks could foster the acceptance and trust for AI among the end-users.

c. Real World Data

Community pharmacists collect and generate real world evidence (RWE) that can contribute to evidence-based health policy and best practices in patient care. For example, data collected during dispensing, practice audits, service evaluation, cost-effectiveness analyses, post-marketing authorisation safety studies, non-interventional and interventional trials and post-marketing authorisation efficacy studies can demonstrate the value that pharmacy services provide in terms of better outcomes and reduced costs for health services.

The potential use of real-world evidence including evidence generation in community pharmacies to evaluate effectiveness and therapeutic added value of innovative medicines in practise should therefore also be rewarded.

As part of the national Health Technology Assessment (HTA) system, real-world evidence could be of utmost importance to inform safety and effectiveness estimates of medicines in clinical practice since it may provide a more generalizable picture of treatment effects in the real world. Additionally, RWE aims to cover not only the safety and effectiveness profile of medicines used under the conditions for which its marketing authorization was granted, but also to characterize its off-label use. This leads to a more comprehensive knowledge about the safety and effectiveness profile of medicines, but also about the (heterogeneous) population using that medications, which should be considered in the risk-benefit analysis and reassessment of the drug.

Real-world evidence is now playing an increasing role in healthcare decisions. The possibility to merge and connect existing health databases is envisaged by the European Commission strategy to boost healthcare data sharing in the EU[18].

PGEU welcomes the Commission's strategy, as 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 when they need to access healthcare services abroad.

EHRs also act as a great source for real-world data. PGEU believes that linking EHRs with ePrescribing systems allows healthcare professionals involved in patient care to access the necessary patient's information, subject to the patient's consent, and thus will further facilitate the use of real-world evidence in digital health.

Community pharmacists have a crucial role to play in avoiding, reporting or mitigating medication errors in practice; they report ADRs to regulatory authorities and implement risk minimisation measures in practice. [19] This contributes to the EU pharmacovigilance system and improves the knowledge base of the safety of medicines on the market, including when medicines are provided at a distance or online. Integrating real-world data on pharmacovigilance, adherence, and effectiveness of medicines into practice, to improve safeguarding and advice on the safe use of medicines for each individual patient, is widely welcomed by community pharmacists. However, it also needs to be ensured that pharmacovigilance tools are accessible and convenient to use for community pharmacists in daily practice. Community pharmacists should also be better integrated and consulted to implement risk-minimisation measures at national and European level.

Moreover, in the healthcare landscape, community pharmacies often collect data of the several health

services they provide to an enlarged and heterogeneous population. Some examples are the inhalation technique assessment and education to patients with respiratory diseases, medication use reviews for the elderly, screening programs for people at risk, etc.

These real-world data gathered at the pharmacy are of enormous importance for all health systems focused on a patient-centred care approach. Pharmacists, as other healthcare professionals, should be able to access, record and share data on a patients' eHealth solution, which would help to bridge clinical and safety information gaps between providers.

d. Online Pharmacy Services

Community pharmacists acknowledge that in today's digitalised world, many citizens are also looking for certain health related products online, including medicines. Brick-and-mortar community pharmacies across Europe therefore offer in many cases online services for their patients to complement their face-to-face relationship whilst guaranteeing trust, professional advice, and patient safety at all times. As part of this wide service approach, community pharmacies can enable patients to reserve and order their medicines from their trusted local pharmacy online or by telephone and offer remote teleconsultations where necessary.

By providing services via an omnichannel approach for their patients, community pharmacists can ensure that people who are in need or wish to order certain health products and medicines online can do this from a trusted source who is also nearby and easily accessible for any questions or personalised advice. Moreover, due to having access to the patients' medication record and other related health information in full compliance with GDPR rules, community pharmacists perform safety checks when health products or medicines are requested online to ensure that the products are suitable for the patient. Also, for non-medicines, including commonly available food and herbal supplements such as St.

John's Wort (Hypericum perforatum), there can be serious risks for health complications when they are taken by patients with certain conditions (e.g. due to interactions with the medicines of the patient altering their safety and effectiveness profile)[20].

During the COVID-19 pandemic, the digital presence and online services provided by brick-and-mortar pharmacies have been accelerated due to the fact that many vulnerable patients were not able to physically visit their local pharmacy. Pharmacies have rapidly responded to these needs of patients by organising local home delivery services. When patients order a product at their local pharmacy, they often can get it delivered within the same day due to the close proximity and high flexibility of pharmacy teams. Moreover, especially in urban areas home delivery services by pharmacies are often organised through environmental-friendly services such as by bikes[21]. In 5 European countries[22], authorities have also installed new remuneration provisions for such home delivery services of community pharmacies.

For community pharmacies, it is very clear that online purchase of medicines does not replace either the face-to-face contact with a pharmacist, or the role that brick-and-mortar pharmacies play in local communities as the most accessible point of contact

in primary care across the territory. It should also be noted that the online sale of medicines can lead to missed opportunities for early detection of chronic diseases and more generally for health promotion and disease prevention of communities which brick-and-mortar pharmacies are in a better position to offer through comprehensive face-to-face interactions.

In conclusion, PGEU acknowledges the value of the digital presence of community pharmacies for patients. Brick-and-mortar pharmacies are in a better position to offer a healthcare hub where people can, among other services, order health products and medicines online with a trusted multichannel that guarantees a safety check and professional advice by healthcare professionals who know their patients and their families very well across generations and understand their social context and needs. Teleconsultations by community pharmacists can also add value in cases where patients are not able to physically visit their local pharmacy. Moreover, due to their close proximity and high accessibility community pharmacists can offer a more personalised, complete, and more environmental-friendly delivery service to patients compared with large players that solely operate online sale of medicines.

It also needs to be ensured that when providing teleconsultation or online dispensing of medicines, health professionals should follow the same fundamental ethical principles and adhere to the same professional standards as with face-to-face consultations or dispensing.

European Health Data Space

PGEU supports the creation of a European Health Data Space (EHDS) as one of the priorities of the Commission 2019-2025[23]. In February 2020, the European Data Strategy was announced. This Strategy aims to build a single market for data comprising of nine data spaces, including one for health, with sector-specific rules that will allow different users to share data.

We welcome the Commission's general objective of facilitating the access of health data across the Union for well-defined and governed primary and secondary uses whilst ensuring citizens have control over their own health data. PGEU also agrees it is vital to strengthen health systems and the healthcare workforce, including for instances, through digital transformation and by increased integrated and coordinated work among the Member States, as well as through sustained implementation of best practices and data sharing, while respecting the legitimate purpose of the use of health data in line with the General Data Protection Regulation (GDPR) rules and by taking the necessary measures to avoid any misuse thereof. Patients need to be informed who accessed their medical record and when, ensuring that personal health data is used in a manner which is scientifically sound and ethically acceptable.

Community pharmacies will be key stakeholders for the generation and use of cross-border health data within the EHDS framework and therefore have the potential to connect to the EHDS both as data holders (e.g. real-world data on pharmacovigilance) and data consumers (e.g. dispensing of cross-border ePrescriptions when EU citizens travel to another EU country).

In several EU countries, community pharmacies are already connected to the European Commission's eHealth Digital Service Infrastructure (eHDSI) allowing them to dispense ePrescriptions from citizens of certain other EU countries when they are travelling abroad[24].

PGEU welcomes the ongoing roll-out of these services across the EU as an opportunity for safer and more effective cross-border healthcare provision in the EU, under the specific purposes outlined in the EU Cross-Border Healthcare (CBHC) Directive (Directive 2011/24/EU)[25]. When developing guidelines for eHealth, as well as standards for digital health products and services, policy makers are called upon to meaningfully involve their end users.

a. Data Governance & Protection

Sharing patient data needs to go along with strong legal and ethical safeguards as well as security. Governance structures and transparency are essential to supervise the use and re-use of data.

The GDPR underlines that citizens have the right to access their personal data and provides the legal framework for the protection of personal data[26]. Enabling citizens to securely access and share their health data in other Member States is one of the priorities in helping the transformation of digital healthcare. Furthermore, data sharing in the context of the provision of digital healthcare services and products to patients within the EU must comply with the applicable professional ethical requirements.

The EHDS framework will allow public sector entities such as hospitals to share data and also offer to patients the possibility to donate their data for the public good in the name of "data altruism." It will also allow for data holders to restrict the number of people who have access to the data or stop it being transferred to another company. This is important for the healthcare workforce because citizens must be able to have control over their own health data to ensure transparency and cooperation by building trust.

b. Electronic Cross-border Health Services

Based on the existing CHBC Directive Member States collaborate through a voluntary network connecting national authorities responsible for eHealth (the 'eHealth Network'). Ahead of the publication of the EU Health Data Space, an evaluation will be conducted to assess the extent to which the eHealth Network supports and facilitates cooperation and the exchange of health data between Member States. It will also evaluate its efficiency and assess how and to which extent the provisions of the cross–border healthcare Directive are sufficient for the cross-border free movement of digital health services and products[27].

Across Europe, strong differences can still be observed in the roll-out of ePrescription systems. This may result in patients being used to present prescriptions in a digital format to pharmacies in their country of affiliation (e.g. via a smartphone) whilst the pharmacy in the country of visit might not be able to verify its authenticity. This can make ePrescription easily forgeable without a reliable cross-border communication system.

PGEU therefore strongly supports the ongoing development of an interoperable system at EU level

that facilitates the cross-border provision of electronic healthcare services, including the exchange of ePrescriptions, as a mean for safer and more effective cross-border healthcare provision overall in the EU.

Directive 2011/24/EU covers healthcare costs, as well as the prescription and delivery of medications and medical devices, all applicable to accessible healthcare from community pharmacies[28]. The Directive also creates EU rules on a minimum list of elements to be included in cross-border prescriptions and encourages the benefits of eHealth.

PGEU welcomes the review of the Cross-border Healthcare Directive so that EU citizens can access healthcare from community pharmacies in any EU country when they are travelling abroad and can be reimbursed by their home country[29].

Moreover, better access to health data across borders will improve the quality and continuity of care offered to citizens[30]. It will also lead to reduced healthcare costs, for example, by eradicating the unnecessary duplication of medical tests and procedures.

c. Interoperability

Interoperability refers to the basic ability of different computerized products or systems to readily connect and exchange information with one another, in either implementation or access, without restriction[31]. The lack of interoperability is one of the major barriers to the deployment of digital health[32]. eHealth solutions are fragmented at the regional, national and European level as interoperability barriers exist between different solutions, professionals, between professionals and authorities and between regions and countries.

Professional organisations are essential in the development of interoperable systems in order to create a coordinated and collaborative healthcare platform, providing effective healthcare services. Professional organisations offer an existing network of professional and technical expertise which can

take full advantage of the opportunities offered by Information and Communication Technology (ICT), with the view to continuously improve current pharmacy practice and patient-centred care.

Interoperability is also critical for enhancing multi-professional collaboration. Collaboration of healthcare professionals for the creation of the European Health Data Space as well as in areas such as the EHR and ePrescriptions help to provide a continuum of care throughout the different levels and settings within the health system. Additionally, interoperability which has enabled progress in eHealth, should be extended to encompass mHealth. This wider spread of interoperability in mHealth can help community pharmacists to provide patients with the support that they need and ultimately deliver significant benefits to the public.

Digital Services Act

On 15th December 2020, as part of the European Digital Strategy, the European Commission published a proposal for a Digital Services Act package to strengthen the Single Market for digital services and foster innovation and competitiveness of the European online environment across all sectors.

On 8th September 2020, PGEU contributed to the EU consultation on the Digital Services Act (DSA), as part of its impact assessment preceding the adoption of the legislative package, and published a position paper[33] raising community pharmacists' concerns on the impact of the DSA package on the online provision of medicines, particularly in a cross-border context.

PGEU welcomes the review of the current regulatory framework applicable to digital services under the Digital Services Act Package which includes a partial review of Directive 2000/31/EC on electronic commerce ('e-Commerce Directive') with a view to adapt it to the current digital ecosystem. In our view, the Digital Services Act should first and foremost tackle unsafe and illegal products available online, including medicinal and healthcare products, as these are increasingly present online and clearly threaten consumers.

Firstly, we strongly support the principle of "what is illegal offline is also illegal online", as well as the principles of consumer protection which should become guiding principles of the future regulatory framework.

Currently, under the e-Commerce Directive online providers of medicines are subject to the law of the country where they are established (so-called 'internal market clause' or 'principle of country of origin'), as opposed to the law of the Member State where the customer/patient resides (country of destination). The e-Commerce Directive authorises Member States to derogate, on a case-by-case basis, from the internal market clause. However, such a derogation is subject to a cumbersome ex ante notification procedure, which clashes with the precautionary nature of national measures envisaged to protect public health, such as those intended to ensure the reliability and quality of the provision of medicinal products to the public.

As permitted by EU law, Member States have adopted different approaches regarding the conditions for the online provision of medicines (including advertising rules), according to the specific realities and needs of the populations living in their territory. This may lead to patients being less protected when buying medicines online from a provider established in a different Member State than when acquiring them at their local brick-and-mortar pharmacy, without necessarily being aware of it. This undermines national health protection standards and jeopardises Member States' competence to tailor the level of protection of public health they wish to grant to their citizens, as it is recognised by the EU legislator and the jurisprudence of the Court of Justice of the EU[34].

We believe that the rules of the country of destination should prevail in respect of the cross-border online provision and advertising of non-prescription and prescription medicines across the European Union to guarantee patient safety and quality of care according to the level of protection determined by the country where the consumer/patient is. Indeed, patients and consumers must be able to receive the same quality of pharmaceutical services and enjoy the same consumer protection rights regardless the offline or online form used to acquire their medicines.

Cross-border online providers tend to establish in Member States where rules on dispensing of medicines are less stringent having thereby a competitive advantage over local pharmacies based in Member States with more stringent rules. Moreover, citizens are confronted with different jurisdictions they are not familiar with. The principle of subsidiarity, as defined in Article 5 of the Treaty on European Union, which also aims to ensure that decisions are taken as closely as possible to the citizen, is then undermined.

In addition, we believe the proposal for a Digital Services Act is a tremendous opportunity to strengthen the responsibility of online service providers and online platforms, particularly those making available medicines, and improving the enforcement of EU and national rules protecting consumers and public health by ensuring illegal practices are swiftly detected, stopped and sanctioned, where applicable.

Recent investigations conducted in various Member States illustrate the vulnerability of consumers vis-a-vis the illegal provision of medicines by certain online service providers and platforms. Such illegal practices are, in many cases, very difficult to detect or prove by national authorities and, as a result, may remain uncovered and therefore unpunished. Such vulnerability has been exacerbated during the Covid-19 pandemic as coronavirus-related products became very profitable goods, regardless of their efficacy, quality or safety. This led to a number of illegal practices[35] being carried out by online service providers and platforms in respect of such products.

We firmly believe that by making the Member State of destination responsible for enforcing the rules applicable to the dispensing and advertising of medicines within their territory the highest level of protection of public health would be ensured, in line with the principle set by Article 168 of the Treaty of the European Union. In addition, this would facilitate the detection and pursue of illegal practices as the authorities of the country where the illegal conduct was committed will be better placed to act swiftly upon receipt of a complaint. Such an approach would also be in line with the EU Community Code for human medicines (Directive 2001/83) which confirms the jurisdiction of the Member State of destination in respect of imposing effective, proportionate and dissuasive penalties to those online services providers operating on their territory that do not comply with the requirements for selling medicines at a distance established by the Directive[36].

Digital Skills in Community Pharmacy

Although digital skills have always been vital for healthcare professionals to provide patient-centred care using digital platforms, it has become even more apparent during the COVID-19 pandemic that improvements to digital skills training is necessary. Healthcare must be changed in the way it is provided in the community and move from a hospital-centred approach to a patient-centred approach, treating patients as close to their home as possible. This includes the issues surrounding the ever-growing digital world in healthcare, which has left healthcare professionals without sufficient ICT skills. Community pharmacists require the necessary digital skills and infrastructure to use digital platforms in order to provide the latest digitalised care.

The European Commission initiative on the Pact for Skills is a shared engagement model for skills development in Europe, which has a section on health workforce skills[37]. PGEU welcomed the Pact, particularly in relation to digital skills as health services have already undergone significant digital transformation which impacts healthcare delivery. Community pharmacists have adapted to innovative technologies in the areas of eHealth, mHealth and teleHealth, ensuring to keep their ICT skills up to date as much as possible.

PGEU therefore supports EU coordinated strategies that aim to enhance the development of digital skills needed to successfully deploy new digital technologies, such as AI, that aim to improve the quality of care and increase efficiency in Member States' health systems. This includes adequate skills on the governance and use of real-world data in context, big data management, health informatics, digital literacy, and technologies.

According to a study carried out by the European Pharmaceutical Students' Association gathering the opinions and suggestions of 587 pharmaceutical students and recent graduates throughout Europe, around three-quarters of respondents claim to have no or almost no education on eHealth while more than half do not even briefly become aware of the topic during their studies[38]. Moreover, 94% of respondents recognise the role and the importance of digital skills in their lives. They also believe that digital skills will play an immense role in aiding pharmaceutical professionals to adapt faster to changing circumstances, optimise treatments and lower the burden on healthcare budgets, as well as to take the best advantage of technologies.

PGEU believes that improving training for digital skills for healthcare professionals would greatly improve the uptake digitalisation in healthcare. We believe this should be reflected both in the undergraduate pharmacy curricula (including through the revision of Directive 2005/36/EC) and continuous education/professional development programs, as this is necessary not only to reflect technical developments but also to ensure pharmacists are fit to exercise their profession as well as to respond to the European Commission's intention to reinforce digital skills of health professionals[39].

Policy Recommendations

PGEU is putting forward the following recommendations to improve digital care for all patients across Europe and support community pharmacists in providing digital pharmacy services:

1. Advance the uptake of trustworthy digital health solutions in healthcare practice that bring meaningful benefits to patients and healthcare systems by:

1. Engaging with healthcare professionals, including community pharmacists, as experienced end-users to develop digital health policies and services at local, regional or national levels as appropriate to ensure that they are fit-for-practice;

2. Ensuring that patients remain in control of their own health data and that they are able to decide to freely and independently about their treatment, the team of healthcare professionals involved in their care as well as their access points for treatments;

3. Safeguarding equity in healthcare by guaranteeing continued alternatives to digital health solutions for patients with low digital literacy/skills and with limited access to internet and digital tools.

4. Enhancing training opportunities and programmes on digital skills within pharmacy curricula and continuous education/continuous professional development programmes.

2. Support community pharmacists, as trusted sources of health information, to help progress the safe digitalisation of healthcare by:

1. Enabling pharmacists to access and update shared electronic health records, if needed, to identify and address potential medication and patient safety-related issues;

2. Supporting pharmacists in integrating real-world data in their daily practice and connect pharmacies as data holders and consumers within the European Health Data Space infrastructure;

3. Adequately rewarding pharmacists' continuous investment in digital health infrastructures and remunerating community pharmacy services, involving recommending, monitoring and advising patients via digital health tools.

3. Exploit the potential of Big Data & AI in healthcare by:

1. Facilitating the production of data in healthcare, via linking electronic health records with ePrescribing systems allowing health professionals involved in patient care to access the necessary patient's information, subject to the patient's consent;

2. Promoting interoperability of information systems in Europe to foster exchange of data across healthcare facilities;

3. Implementing clear standards, professional and ethical requirements and legally binding assessment criteria to ensure transparency of AI systems in healthcare;

4. Using it to promote more collaboration across many different health professionals serving the same patients as well as to promote integration of primary care systems.

5. Offer training on AI techniques and approaches (e.g. machine learning), initiating at the undergraduate level, which must be supported by appropriate structures in the practicing environment. The healthcare workforce needs to be appropriately trained and financially supported during the introduction and application of AI systems in healthcare settings.

4. Develop trust in the use and re-use of data in healthcare by all stakeholders involved through:

1. Processing patient data under a high level of data protection standards within trustworthy infrastructures that enable the access to secure data services. It also has to be ensured that data access and analysis are amenable to European rules for privacy and data protection;

2. Guaranteeing full compliance with ethical principles;

3. Ensuring transparency and creating adequate governance structures and to supervise the use and re-use of data;

4. Allow for data holders within the European Health Data Space to restrict the number of people who have access to the data or stop it being transferred to another company;

5. Safeguard consumer protection for the cross-border online provision of medicines and digital health services within the EU Single Market by:

1. Adopting the principles of "what is illegal offline is also illegal online" within the review of the EU regulatory framework to deepen the Internal Market for Digital Services under the Digital Services Act Package;

2. Guaranteeing patient safety and quality of care according to the level of protection determined by the country where the consumer/patient is established by exempting the cross-border online provision of non-prescription and prescription medicines from the country-of-origin principle;

3. Strengthening the responsibility of online service providers and online platforms, particularly those making available medicines, and improving the enforcement of EU and national rules protecting consumers and public health by ensuring illegal practices are swiftly detected, stopped and sanctioned;

4. Introducing effective cooperation and enforcement procedures for cross-border issues in the regulation and oversight over digital services;

5. Creating a level playing field in the internal market between the platform economy and the "traditional" offline economy, based on the same rights and obligations for all interested parties;

6. Broadening the scope of the e-Commerce Directive for this to apply to online suppliers established outside the Union that offer products, including medicinal products, online to European consumers;

7. Increasing awareness in collaboration with pharmacists' organizations on the common EU logo enabling the identification of legitimate internet sellers of medicines as well as on messages as to how to distinguish illegal sites as well as active prosecution of marketplaces that do not respect regulations and legal requirements by the competent authorities.

Annex: Best Practices from community pharmacists

a. eHealth

Denmark: Shared electronic Medicine Card

In Denmark the ePrescription system has been taken a step further. A shared electronic Medicine Card has been established. Every citizen has an electronic medicine card which holds current and previous treatments and the corresponding medications. All parties in the health sector (doctors, hospitals, pharmacies, home care personnel etc.) have access to relevant parts of the data and obligations to ensure that the data handled by them is up to date. Less than 1% of the Danish prescriptions are now non-electronic.

France: The Dossier Pharmaceutique: a medicines safety system to ease communications between community

The Pharmaceutical Record (Dossier Pharmaceutique or DP), initiated and implemented by the French Chamber of Pharmacists, was created by law in 2007. Primarily designed as a tool to avoid medicines interactions and redundancies, the DP is an electronic record shared between all French community pharmacies, which displays all treatments dispensed to a given patient over the last 4 months, regardless of the pharmacy where they were delivered. To date, around 38.5 million French patients have a DP. An application is currently being developed to give patients direct access to their DP.

Data on most medicines are kept for a maximum period of 4 months, but data on biological medicines are retained for 3 years (because they require special monitoring), while data on vaccines are saved for 21 years (in order for pharmacists to be able to tell their patients whether they need to get booster shots). Patients give their consent for the creation and use of their DP, as well as for the registration of medicines which are dispensed to them. They can oppose the registration of any medicine they do not want to be recorded and can ask for the termination of their DP at any time.

After a pilot phase, the DP has also been deployed in French hospital pharmacies and hospital medical services (anaesthetics, emergency services, geriatrics, etc.) with the same functionalities as in community pharmacies, with a view to improving the coordination of care and facilitating the collection of accurate information on patients.

As of June 2021, 99.9% of French community pharmacies (21,192 pharmacies) and 19.1% of French hospital pharmacies (497 pharmacies) are connected to the DP.

The DP uses an IT communications network connecting pharmacies (the DP system), allowing further services connected to medicines safety. It currently supports three other services (DP-Alertes, DP-Rappels, DP-Ruptures), intended to facilitate direct and timely communication between French community pharmacies, national health authorities, hospitals, wholesalers and pharmaceutical companies:

1. Since July 2010, the "DP-Alertes" service enables the French Chamber of Pharmacists to disseminate safety alerts to all French community pharmacists (who are informed within 35 minutes), so that they can provide all patients concerned with relevant information and advice. In 2020, 82 safety alerts were issued via the DP (7 in 2019).

2. Since November 2011, the "DP-Rappels" service also enables the French Chamber of Pharmacists to notify batch recalls and withdrawals to all French community pharmacists, so that they can immediately check their inventory and remove from sale all medicines concerned. In 2020, 32 recalls were notified via the DP (51 in 2019).

3. Since March 2013, the "DP-Ruptures" service can be used by community and hospital pharmacists to report medicines shortages to pharmaceutical companies and to the French Medicines Agency, so that they can understand the situation, find alternative solutions and ensure continuity of treatment. When community pharmacists cannot get the product that they requested from their wholesaler within 72 hours, their pharmacy dispensing software (connected to the DP) automatically notifies the pharmaceutical company concerned, which has to provide an answer. As of June 2021, 19,275 French community pharmacies, 742 hospital pharmacies, 32 wholesalers and 86 pharmaceutical companies use the "DP-Ruptures" service.

The Netherlands:

Secure exchange of healthcare data

The broadly supported (patients, government, health providers and health insurers) MedMij initiative ensures that anyone who so wishes has access to their health data in a personal health environment (in Dutch: PGO, Persoonlijke Gezondheids Omgeving) of their own choice. This can be an app or a website, for example. To enable this, such an app or site must be able to communicate securely with all the locations where the information is stored. These could be the healthcare information system of a hospital, the physician, and the pharmacy.

MedMij is the standard in the Netherlands for the secure exchange of health data between care users and care providers: https://www.medmij.nl/en/

Clinical risk management on medication use Dutch community pharmacies

Since the introduction of computers the clinical risk management on medication use has been developed in the Netherlands over the past 35 years. This has led to a safer use of medicines and the pharmacist has developed clinical risk management with monitoring on dosing, drug-disease interactions (e.g. chronic diseases, renal functions, etc.), duplicate medications, drug-drug interactions, drug intolerabilities, etc.. The clinical risk management is incorporated in the dispensing process and the pharmacy information system is supporting the pharmacist in this task with alerts. More and more patient data has become available to pharmacists, such as laboratory data/clinical data (e.g. cholesterol, HbA1c, blood pressure, renal function and pharmacogenetic parameters). In recent years, therefore, pharmacists have access to tools as clinical decision support systems with embedded clinical rules to support pharmaceutical care, alongside traditional clinical risk management on medication use. Clinical rules combine all available patient data, making it possible to identify new risk situations. The pharmacist receives more specific and relevant signals than with traditional clinical risk management and can concentrate on the high risk alerts, promoting a more personalized pharmaceutical care for every patient.

National drug database G-Standaard in The Netherlands

G-Standaard, the Dutch drug database which is used by all parties in healthcare in the Netherlands. The G-Standaard contains all the products that are dispensed by or used in the pharmacy. It enables an efficient exchange of information between healthcare parties. The G-Standaard covers information about licensed medicines; unlicensed medicines (e.g. raw materials and compounding preparations); vitamins and other nutritional supplements; homeopathic medicines; and medical devices. More than 100.000 care products are registered in G-Standaard. To each care product information is added, for example about clinical risk management (dosing controls, drug drug interactions, pharmacogenomics, etc.), recommendations of aRMM, pharmacovigilance, price, logistics and the reimbursement policy of various health insurers. The pharmacotherapeutic information (clinical risk management, recommendations of aRMM) in the G-Standaard is provided by the Medicines Information Centre of the Royal Dutch Pharmacists Association (KNMP).

Portugal: Integration of community pharmacies in national databases

eBoletim de vacinas (electronic vaccines record):

Administration of flu vaccines at Community Pharmacies are automatically registered in the individual electronic vaccines record. This is a similar process to other healthcare facilities, integrating community pharmacies in the national vaccination database.

SIVAVE (COVID-19 Tests Database):

Community Pharmacies are integrated in the national reporting system of COVID-19 tests. All the Covid-19 tests performed at the pharmacy and the respective results are registered directly into the National database and shared with health authorities.

e-Prescribing

Following successful pilot projects, the national roll-out of e-prescribing ("Receita sem papel") began in 2013 with a pilot deployment in three towns (Ponte de Lima, Setúbal and Figueira da Foz). In 2015 the successful national roll-out was achieved (taking approximately six months). During this transition stage, paper-based prescriptions existed side by side with electronic prescriptions. In 2016, full e-prescribing deployment with total paperless prescription was reached. Five years after, e-prescribing accounts for more than 90% of all medical prescriptions.

Other efficiencies have been achieved including streamlining of internal processes for prescription handling (lower cost, lower burden), invoicing and reimbursement claiming. The e-prescription system is integrated with the reimbursement system for calculation and claim functions; consequently, pharmacists experience a significant decrease in discrepancies with paying entities compared to the previous system. Another benefit to e-prescribing is improved compliance with regulatory authority rules as the calculation/validation is done online. This means that dispensing information registered in the national e-prescribing system is all registered in real time.

The role of e-prescription is fundamentally simple and a powerful and important innovation for all players. It allows the transmission of prescription messages and digitally signed prescriptions from primary care prescribers to a central network, where they can be accessed by the pharmacy dispensing the medicines to the patient. Prescriptions are then subsequently passed on electronically to NHS prescription services for reimbursement.

Potential Benefits:

1. NHS:

- Better expenditure control
- Better control of illegitimate prescriptions and fraud situations
- Reduction of costs with prescriptions assessment

2. Physicians:

- Improves access to data and clinical decision support to prescription
- Better information on whether or not their patients get medication

3. Patients:

- Enhanced safety of medication management
- Reduction of medical errors and adverse drug effects
- Therapeutic records
- Safer prescription and supply of medicines
- Future undividualized reimbursement schemes depending on patient variables

4. Pharmacists:

- Reimbursement claims validted in real time
- Reduction or elimination of administrative tasks related to prescription/invoicing validation at the pharmacy
- Improvement of dispensing safety
- More accurate information on patients
- Prescription data can be stored securely and communicated to other members of the healthcare network without the risk of paper records being lost.

Sweden

ePrescription, database of all electronically stored prescriptions/National Medicines List (NLL)

ePrescriptions make out more than 99 % of all prescriptions I Sweden. All ePrescritpions are stored in a national database available for all pharmacies. The prescriptions are stored electronically in the database for the entire time of validity and when dispensed from the prescription in the database is updated. Since 1st May 2021 the pharmacies has to transform a prescription made on paper to an electronical prescription in the database. From 10th May 2022 all prescriptions have to be ePrescriptions, with only a limited number of exemptions. When dispensing a prescription, the pharmacist must take all electronically stored prescriptions in consideration. The patient can access all valid prescriptions in the database via the e-Health Agency or via the pharmacies' webpages/e-pharmacies after logging in with BankID (e-identification). The prescription database makes it easy for the patient to order prescribed medicines online in a safe and controlled way.

All dispensed medicines are stored in a database that is available for the pharmacies, the prescribers, and the patient. The patient can access the list of dispensed medicines via the e-Health Agency or the pharmacies' webpages.

From 1st May 2021 to 30th April 2023 a transformation of the two databases (prescribed and dispensed) into one is taking place. The new database is called "National Medicine List" (Nationella Läkemedelslistan, NLL). When the transformation is completed the prescriber and other health care personnel will be able to see both prescribed and dispensed medicines. The prescriber will also have the possibility to withdraw and update the prescriptions in an easy way. The prescriber can also see changes lade by the pharmacies. The patient can access the combined list of prescribed and dispensed medicines via the E-health agency and the pharmacies' webpages.

Electronical Expert System (elektroniskt expertstöd, EES) – a pharmacy decision support system

All pharmacies in Sweden have access to a decision support system called EES. EES analyses all electronically stored prescriptions in relation to the patients age and sex. EES signals if there are any issues that the pharmacist must consider. This can be interactions, inappropriate dosing, inappropriate medicines for elderly, two medicines with the same effect etc. It also contains special information for dosing to children etc.

The pharmacist assesses the relevance of the signal and if needed the pharmacist collects more information from the patient or the prescriber. Some signals are not clinically relevant, as interactions where the dose have been adjusted etc. but in some cases there is a real problem that has to be handled. The pharmacist can then clarify the prescription, cancel/delete the prescription or advice the patient how to proceed. When the signal is handled or clarified the pharmacist can "close" the signal so the next pharmacist dispensing to the same patient will not see the handled signal.

The pharmacies use EES in more than 60 % of all customer interactions. EES is used both by brick-and-mortar pharmacies and e-pharmacies.

b. mHealth

Denmark: Danish Pharmacy App and Websites

The Danish pharmacies' new app "apoteket" makes life a little easier for persons under regular medical treatment – from birth-control pill users to chronically ill persons.

The app brings all information about your medicine together. The app is connected to all relevant systems, from The Shared Medicine Card to the pharmacies' storage systems.

Among other things you can in the app repeat prescriptions, see subsidy status and price, establish a fixed medicine order and be assisted in correct taking of your medicine. The most unique feature of the app is that you can see, if your preferred pharmacy has the medicine you need in stock. If not, the app will direct you to other pharmacies nearby having the medicine in stock.

The app will generate better compliance, as medicine users will be reminded when it is time to renew a prescription and time to fetch your medicine or choose to have it delivered. You can also choose a fixed order at the pharmacy and then it will take place automatically. Furthermore you can set the app's medicine reminder to let you know when it is time to take your medicine.

Apoteket.dk

Apoteket.dk is the shared website of the Danish pharmacies. Here you can find information on health and illness. Citizens can find advice on self-care and chat with the pharmacy day and night. Citizens can also find information on all medicine products available in Denmark.

The chat at apoteket.dk

Danes with healthcare questions can chat with pharmacists or pharmacy technicians via computer, tablet or mobile phone at apoteket.dk day and night.

It is important that pharmacy counselling is easily available for as many people as possible. The pharmacies are of course ready to counsel at the pharmacy counter – however, the pharmacy must also be available online. Just as the Danes very much are. The service is free of charge, open for all and the response time is fast.

Portugal : App "Farmácias Portuguesas"

Portuguese pharmacies have an app that brings the pharmacy and the pharmacist closer to the patient.

The app "Farmácias Portuguesas" expands pharmaceutical services across the country for all patients who are looking for the nearest open pharmacy or indeed a specific one for a number of services. The app can be used to aid the purchase health products or medicines (non-prescription medicines), to find information concerning medicines and to manage one's health. Depending on the availability of the chosen pharmacy, the user can receive non-prescription medicines at home. The App also allows the user to find the nearest pharmacy.
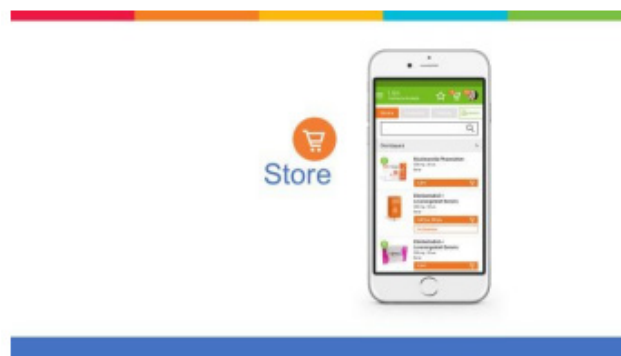
1. Pill Reminder

Additionally, this app also shares therapeutic reminders, following the pharmacist creation of certified treatment plans with direct integration in the app. It is also possible to send refills reminders:

- A Pill Reminder that creates a plan for medication intake for the user (or a family member) which controls the frequency, amount and the time of the next intake;

- "Saúde de A a Z", which allows the user to access useful and accurate information on medicines or wellbeing, separated into multiple categories for easier retrieval, ensuring the information is transmitted correctly to patients and, therefore, contributing to the strengthening of the relationship between the patient and the pharmacy;

- A personal area with a record of the user's biometric and clinical parameters, such as body mass index (BMI), waist measurement, blood pressure, cholesterol, triglyceride and glucose levels, all of these being evaluated in the app and alerting the user for any value out of the standard range that requires further attention.

Portugal: 1400 website and support line

The 1400 support phone line is now available as a website. The 1400 support line has already supported over 50.000 Portuguese citizens and registered over 10.000 medicine orders, that were home delivered or collected at the preferable patient's Pharmacy.

This project was initiated as a pilot in the northern region of the country, in a partnership with the Northern region Health Authority and the Health Ministry. In March 2020, with the sanitary emergency of the COVID-19 pandemic, this project was extended to the whole country.

The 1400 Support Line establishes the contact with the patient's' preferred pharmacy. Patients can order their medicines from their preferred pharmacy, to be collected at the pharmacy or delivered at home, 24 hours a day, 7 days a week, 365 days per year. The 1400 support line also helps people to get hold of urgent medicines. The phone line is free of charge to users.

Through 1400 website and phone line it is also possible to identify community pharmacies on duty.

Patients can also talk to their pharmacist, guaranteeing access to specialised advice on medicines. This support line has an average of 209 daily phone calls. The promotion and execution of this project counts with the collaboration of the country's Regional Health Administrations.

c. Artificial Intelligence and automation in pharmacy practice

Portugal: Sifarma Clínico

Portuguese Pharmacies use a new pharmacy software module to support Professional Intervention. This module allows the registration of clinical information from patients (with their consent) for purposes of follow-up and monitoring in community pharmacy. Sifarma Clínico is prepared to share patients' information with other healthcare professionals, improving communication and collaboration in a multidisciplinary context.
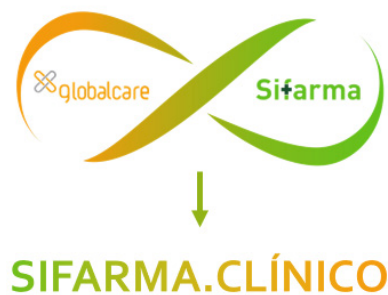
The Sifarma-Clinico, allows for the following:

- Clinical Pathways, clinical information structured in order to make similar Pharmacies' professional intervention, as it happens in the flu vaccine intervention.

- Clinical Process of patients documented and stored in Sifarma.Clínico, in order to support new models of dispensing medicines and healthcare services.

- Holistic view of the person in an integrated way with Health Units.

- Management of the pharmacy services calendar.

- Standardization of clinical terminology between pharmacies and health units.

- Bidirectional of clinical information between Pharmacies and Health Units.

d. Integration of real-world data and evidence in community pharmacy

The Netherlands: Dutch Foundation for Pharmaceutical Statistics SFK

In the Netherlands, 99% of community pharmacies are voluntarily connected to the Dutch Foundation for Pharmaceutical Statistics (SFK)[40], which has been set up by the Royal Dutch Pharmacists Association (KNMP). The SFK collects exhaustive data about the use of pharmaceuticals in the Netherlands since 1990, coming from about 15.8 million people and involving 240 million dispensing activities of medicines and medical devices per year. In addition, SFK collects weekly data from wholesalers on which medicines are not directly available for pharmacists.

For each dispensation, the SFK registers information about the drug supplied, the prescribed daily-dosage, the dispensing pharmacy, the health insurance company that does or does not reimburse the remedy, the prescribing doctor and the patient for whom the

prescription was issued. With this, the SFK has the most elaborate collection of data in this field in the Netherlands. The dispensing data is owned by SFK, with a supervisory board of actively practicing pharmacists who control what may and may not be done with the data. Individual pharmacy-data is never shared with third-parties. Thorough validation routines and well-tried statistical procedures guarantee the high quality and representativeness of the SFK-data. With regard to the registration of data concerning drug consumption, the SFK pays a great deal of attention to the privacy of the parties involved. Privacy regulations guarantee the privacy of the participating pharmacists. The SFK never shares information about individual docters, although they are identifiable in the dataset. With regard to the

patient, SFK only gathers pseudonymised information, which cannot be used to directly identify a patient. This information will never be shared with anyone besides the original dispensing pharmacy.

The SFK uses the dispensing data to develop feedback reports to the individual community pharmacy. There are reports about rational use of medicine, adherence therapy, deprescribing, cost of medicines reports, quality of pharmaceutical care, etc. Moreover, the dispensing data are also used to develop relevant reports for the health authorities (Ministry of Health), to support scientific research on a broad range of topics (e.g. the over-use of opioids) and to support the activities of the KNMP.

Portugal: HiCorr-Flu and COVID-19

One of the most challenging aspects of public health surveillance of seasonal influenza are the early identification of the outbreak and peak of the epidemy, and the estimation of its impact in the health care system. Though detection and tracking of this infectious disease primarily relies on physician diagnoses, sentinel influenza-like-illness (ILI) surveillance and virologic confirmation, other non-traditional data sources, such as community pharmacies' dispenses, have been shown to provide accurate and more timely detection.

Consequently, surveillance systems developed based on this data are able to anticipate the load on primary care services and hospitals.

Figure 1 (below) details the output of the HiCorr-flu model, a surveillance systema based on community pharmacy data which is able to anticipate the beginning and the peak of the flu epidemic in approximately two weeks, when compared with physician's diagnosis in primary care.
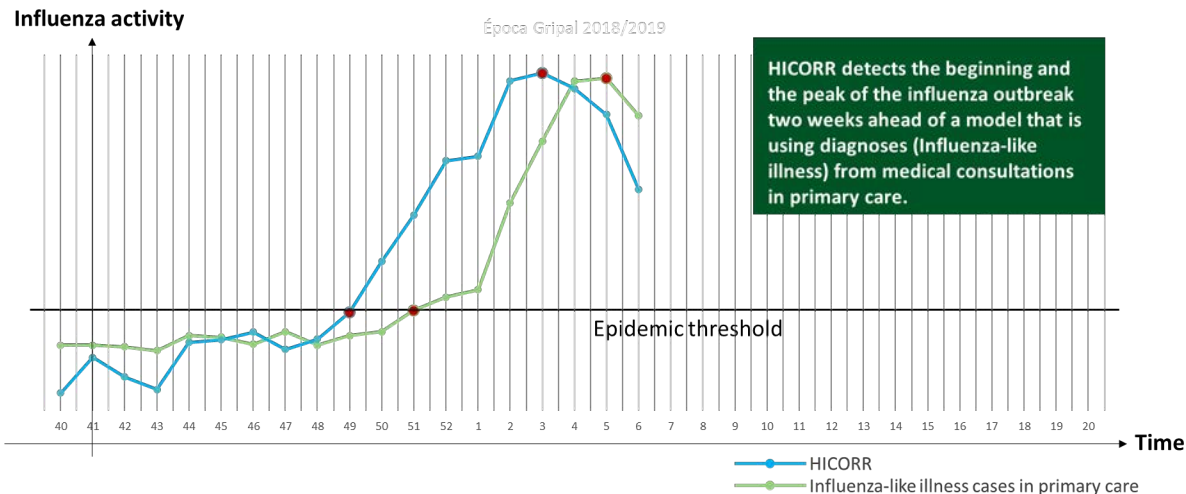

Figure 1. HiCorr-flu model.

These results are of major importance as it supports the community pharmacy' role on public health, as sentinel network for influenza epidemic surveillance, and allows healthcare organizations and public health agencies to anticipate measures to tackle the impact of the epidemic on health.

Another feature of HiCorr-Flu is the ability to give information about the epidemic activity at a local, regional and national level, which is of fundamental importance to adapt the measures to the activity felt in each setting (Figure 2).

Figure 2. HiCorr-flu epidemic activity.

HiCorr-COVID19

The epidemiological situation caused by the new coronavirus (SARS-CoV-2), which generated the outbreak of COVID-19, was declared a pandemic by the World Health Organization (WHO). In this context and in large-scale community transmission of SARS-CoV-2, public health surveillance is of major importance to anticipate, prevent and prepare health care response to future outbreaks.

Literature have shown that community pharmacies' data can be used to detect and anticipate infectious diseases outbreaks of respiratory and gastrointestinal diseases. The same strategy can be used to develop systems capable of anticipating the load of COVID-19 outbreaks in primary care services and hospitals using epidemiological models applied to that data.
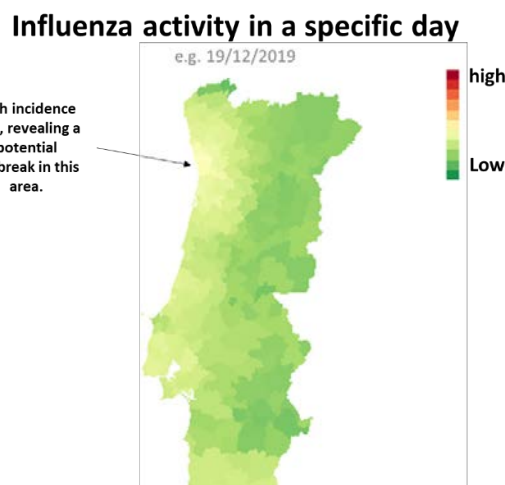
The model was used to assess if community pharmacies' data was able to anticipate the biggening of the COVID-19 outbreaks.

Figure 3 (below) overlap of daily pharmacy sales data and new-confirmed COVID-19 cases, lagging 15 days, in the period previous to the outbreak of COVID-19 in Portugal and before the announcement and implementation of government public health restrictions.

This example shows high and statistically significant correlations between community pharmacies data and COVID-19 cases, suggesting the ability to anticipate the epidemic beginning.
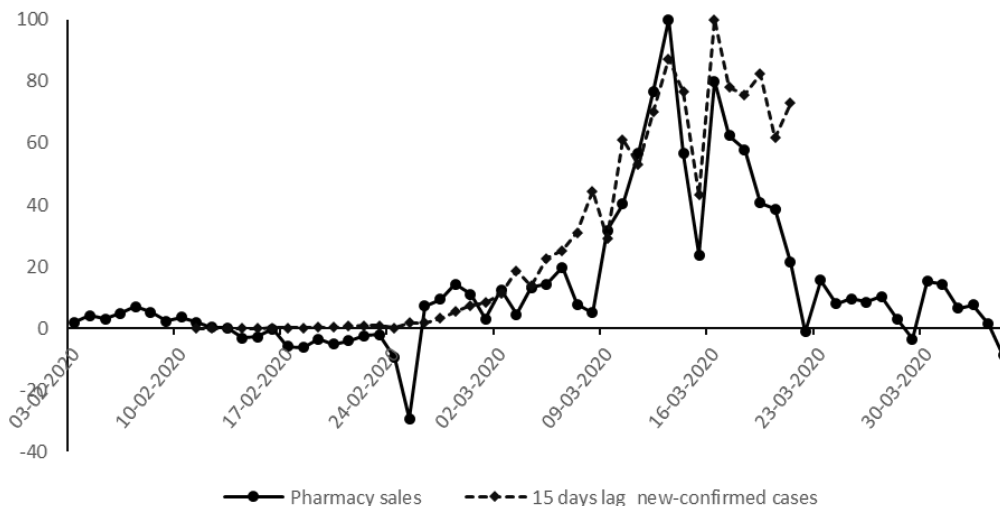

Figure 3. Overlap of daily pharmacy sales data and 15 days lag new-confirmed COVID-19 cases.

e. Other relevant technological advancements in pharmacy practice

Italy: Pharmacies as access points for telehealth services

For many years Italian pharmacies are fully engaged as an important electronic point of access for the healthcare system by means of the CUP (Centro Unico Prenotazione) project active in most of Italian Regions. An Italian patient can go the nearest pharmacy in order to book and pay a visit to a NHS specialist doctor or different health tests in an NHS point of care or in a private accredited laboratory.

It is a great opportunity for patients with low computer literacy to get the NHS contact nearest to their home in order to book and also bring back medical exams. The CUP network is also used in some Italian regions to help citizens to book COVID-19 vaccines for the administration in hospitals and other vaccination centers. According to the latest data of Federfarma, nearly 65 % of community pharmacies offer the CUP service to their patients.

In addition, Federfarma activated some years ago an own national platform for telemedicine services that now is involving about 5,400 community pharmacies (29% of Italian pharmacies) working towards a pro-active prevention of cardiovascular diseases.

According to the latest data, through the telemedicine service pharmacies managed to complete in 2020, 140,370 different sessions of heart and blood pressure monitoring. Even though in 2020 the COVID-19 outbreak forcedly restricted freedom of circulation of Italian people with a severe first lockdown in spring 2020, the telemedicine performance decreased only of 8 %. This perfectly shows how important it is to develop instruments of telehealth as near as possible to the patient's home.

The telemedicine service has demonstrated to offer a great value for pharmacy patients. In Q4 of 2020, 12,9 % of people subject to ECG Holter were asked to refer to his/her GP for further checks.

65 % of community pharmacies offer the CUP service to their patients.

29 % of community pharmacies as involved in prevention of cardiovascular diseased through telemedicine services.

140,370 different sessions of heart and blood pressure monitoring were completed as part of telemedicine services in 2020.

12.9 % of people subject to ECG Holter were asked to refer to GP as part of telemedicine services in Q4 of 2020.

The Netherlands: VIPP (Acceleration Program Information Exchange Patient and Professional) Pharmacy

The Dutch Ministry of Health has approved an incentive ICT program to stimulate ICT (VIPP Pharmacy incentive) in the community pharmacies[41]. This program is announced by the Dutch government on 1st April 2020. The total subsidy is 86 million euros.

In VIPP[42] (Acceleration Program Information Exchange Patient and Professional) Pharmacy, the focus is on the implementation and use of the information standards for medication data by pharmacies, the exchange of this data with the patient and the pharmacovigilance of pharmacies.

The program consists of three substantive modules:

1. Implementation and use of medication standards in pharmacies.

2. Disclosure of medication data to the personal health environment of patients.

3. Implementation of a new clinical risk management system in pharmacies.

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