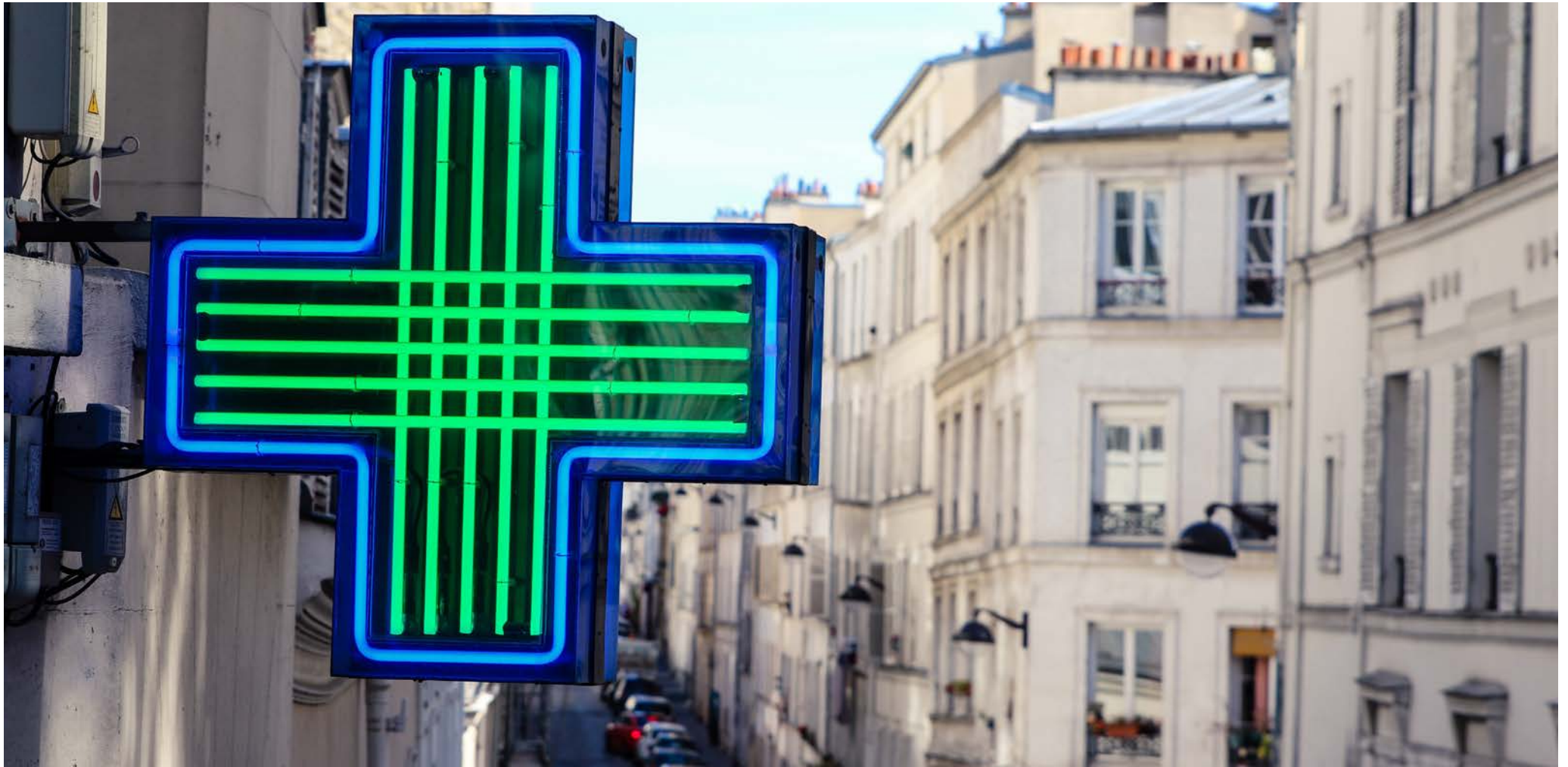# Position Paper on Electronic Product Information

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

PGEU strongly supports the use of electronic Product Information (ePI) as a tool complementary to current printed leaflets. Indeed, maintaining printed material bound up to the box addresses the paramount need for immediate and equal access to information crucial to minimise risks, regardless of the equipment and ease with technology.

As a complementary tool, the ePI could increase citizens' access to objective and neutral information on pharmaceuticals at home, improving confidence and patient empowerment. In addition, due to its semi-structured and accessible format and design, ePI also has opportunities to improve readability and engagement of citizens to important information on pharmaceuticals and meet specific patients' needs such as those with impaired sight and low literacy levels. The ePI also offers additional opportunities for better linkage to and visualisation of risk-minimisation information. Another promising feature is the integration, where applicable, in eHealth systems such as electronic health records and e-prescribing systems.

European community pharmacists are committed to contribute to an appropriate and timely implementation of ePI in their practice. However, in the ongoing implementation process, several key conditions need to be met to ensure that it will optimally be deployed as a trustworthy means of expanding access to information on medicines. Firstly, it should be ensured that ePI is used for the delivery of regulator-approved medicine product information only and that it will not be used to deliver promotional information. It therefore needs to be ensured that third-party applications do not store any personal information linked to the request of accessing ePI for a specific medicine. Moreover, citizens, using the various technologies and applications to access

ePI as an intermediate, should be directed to independent sources only, such as the official websites of the European Medicines Agency (EMA) and/or national competent authorities (NCAs).

As trusted experts in medicines, the most accessible group of healthcare professionals in Europe and often the last professionals that patients see before taking their medication, community pharmacists commit to continuing advancing their role in the provision of comprehensive information on medicines to patients, also beyond the implementation of ePI in their practice. This paper highlights several successful initiatives that pharmacy organisations across Europe have developed to complement the product information leaflet (PIL) and outlines several professional services that community pharmacists provide to improve the use of medicines through increased literacy.

Introduction

The product information (PI) of a medicine includes the package leaflet for patients and the summary of product characteristics (SmPC) for healthcare professionals. These documents accompany every single medicine authorised in the EU and explain how it should be prescribed and used.

In January 2020, the EMA, Heads of Medicines Agencies (HMA) and the European Commission published key principles outlining a harmonised approach to develop and use electronic product information (ePI) for human medicines across the European Union[1]. The key principles describe the benefits ePI can deliver for public health and the efficiencies it may introduce in regulatory procedures. They explain how ePI will comply with the existing legislative framework: it will be provided as open access information that complements the paper package leaflet[2].

This publication forms the basis of follow-up implementation plans for ePI in accordance with applicable EU legislation. The Pharmaceutical Strategy for Europe[3], published in November 2020, highlights that better use of product information in electronic format (ePI) could facilitate the delivery of information on the medicine to healthcare professionals and patients in the EU's multilingual environment and support a wider availability of medicines across Member States. It also stresses that any measures should take into account the needs of all patients and healthcare professionals. As one of its key actions on regulatory efficiency, it foresees to develop and implement electronic product information (ePI) for all EU medicines with involvement of Member States and industry, and evaluate and revise relevant provisions in the legislation in 2022.

In the light of these key developments, PGEU outlines in this paper its position and recommendations on key aspects of ePI for the future whilst providing an overview of the community pharmacy contribution in improving information on medicines across Europe.
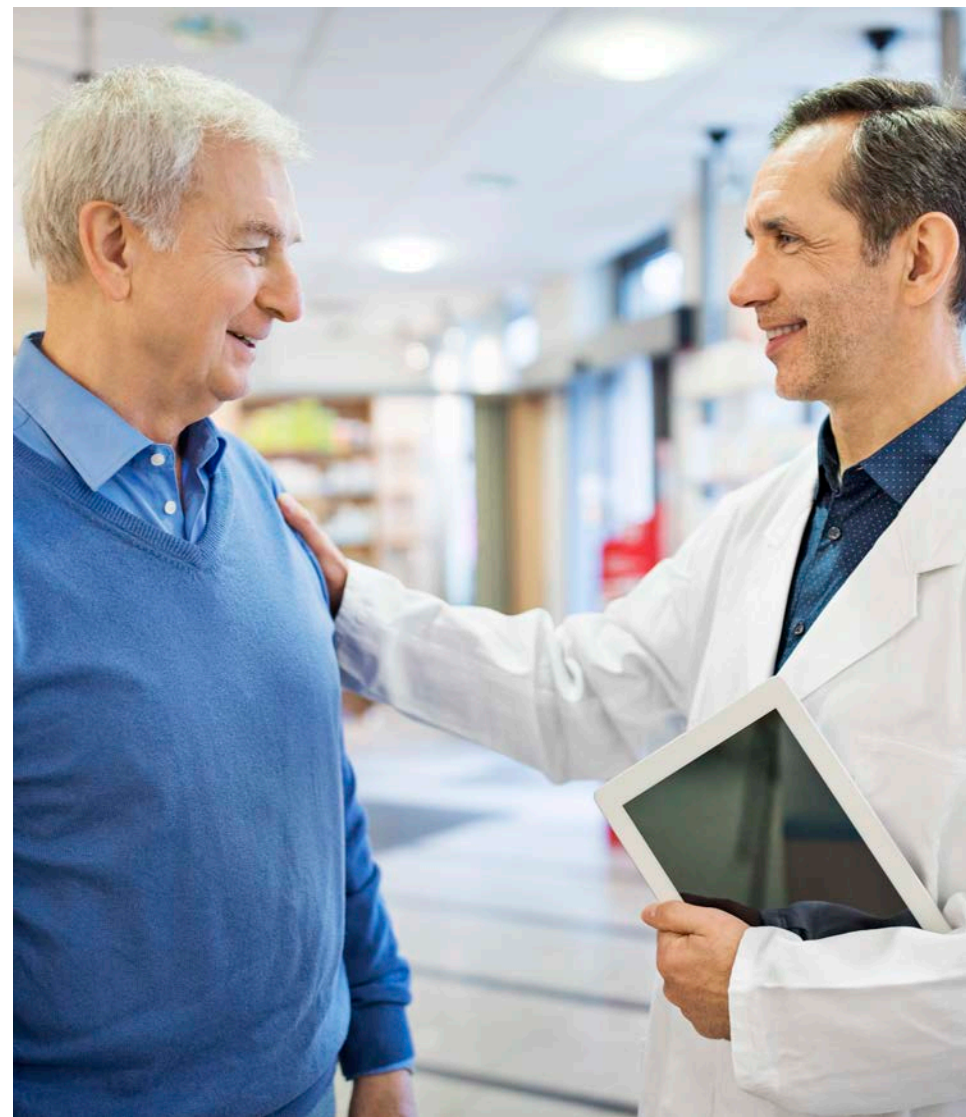
Key Principles For The Implementation of ePI

Expanding access to information on medicines as a public health imperative

PGEU welcomes the use of electronic Product Information (ePI) as a complementary tool to increase citizens' access to objective and neutral information on pharmaceuticals at home, improving confidence and patient empowerment.

In addition, due to its semi-structured and accessible format and design, ePI also has an opportunity to improve the readability and engagement of citizens for important information on pharmaceuticals. The ePI also offers additional opportunities for better linkage to and visualisation of risk-minimisation information.

Complementing the paper package leaflet

Today, the package leaflet is widely used to complement information received from healthcare professionals for a very diverse group of citizens, including parts of the population with limited access to digital tools such as certain elderly citizens and people with limited financial resources. Due to its importance, it is crucial to ensure that at all times, product information is made universally and instantly accessible, both for prescription and non-prescription medicines. Indeed, in line with the ongoing work at EMA on risk minimisation measures, access to essential information (contra-indications, dosage, adverse effects, etc.) should not be weakened in any way.

Moreover, the European Medicines Agency (EMA), Heads of Medicines Agencies (HMA) and the European Commission reinforced the value of the paper package leaflet for patients / consumers with low digital literacy (low ability to use digital devices effectively) or limited internet access in their 2020 Joint Key Principles for ePI[1].

Printing product information in community pharmacies – an unworkable situation

It has been recommended by some stakeholders to fully replace the paper package leaflet with the electronic product information in the future, despite recent agreement at EU level that the ePI should only be used to complement the paper package leaflet[1].

In order to give access to paper product information for people who cannot access ePI, it is suggested that pharmacists and pharmacy teams could print the product information from pharmacies. From the pharmacy perspective, this would be an unworkable and disproportionate requirement, which would take away precious time from pharmacists to provide patient care. The PGEU Medicine Shortages Survey 2020[4] results indicate that community pharmacists across Europe already spend on average more than 6 hours per week dealing with shortages.

Data from the United Kingdom show that a pharmacy dispenses on average around 300 prescription items per day[5] . Community pharmacists expect that the majority of their patients would request for the patient information leaflet to be printed at the pharmacy if it was not already included in the package. Therefore, it could be envisaged that over 400,000 community pharmacies in Europe would be requested to print possibly hundreds of paper package leaflets for each medicine every day, with every paper package leaflet consisting of multiple pages of paper in A4 format, noting that many patients are on multiple medications. In addition to causing serious workflow disruptions and delays in the delivery of medicines to patients, it would also place an unsensible financial burden on pharmacies and a responsibility that is today a key regulatory obligation for pharmaceutical companies.

Accessibility to patients/consumers with diverse abilities

PGEU acknowledges the opportunities that ePI can offer to meet specific patients' needs such as those with impaired sight and low literacy levels. However, it should always be considered that some of these vulnerable patients have limited access to digital tools and lack digital skills too.

It should therefore be ensured that the ePI strategy is part of a wider strategy on improving universal accessibility to product information for patients with diverse abilities.

Open access to regulator-approved information only

PGEU supports that ePI is intended for the delivery of regulator-approved medicine product information only, that it will not be used to deliver promotional information and that it should always be published as open data, freely accessible for use and reuse.

To ensure that ePI remains a source of trusted and non-promotional information, it will be crucial that citizens, using the various technologies and applications to access ePI as an intermediate, will be directed to independent sources such as the official websites of EMA and/or national competent authorities. It should also be ensured that third-party applications do not store any personal information linked to the request of accessing ePI for a specific medicine, which could then potentially lead indirectly to promotional activities.

Data protection

It should be ensured that third-party applications do not store any personal information linked to the request of accessing ePI for a specific medicine, which could then potentially lead indirectly to promotional activities.

At the same time, it must be clarified how software, apps or websites will process and store citizens' data when searching for a medicine's ePI – be it a search query or by scanning a medicine's barcode linking to the ePI.

The appropriate application of European and national data protection legislation should be guaranteed and closely monitored in these third-party applications or websites at all times.

Governance

PGEU supports that ePI will be made available to users through websites at EMA and NCA level. We also welcome the integration, where applicable, in eHealth systems such as electronic health records and e-prescribing systems.

This refers both to public and private e-Prescription systems which co-exist in some European countries. Today, the Summary of Product Characteristics (SmPC) information is already directly electronically available in software

programmes and/or applied in scientific databases of healthcare providers in several EU countries. This improves the user-friendliness and accessibility of product information for healthcare providers.

Flexibility in implementation

PGEU welcomes the acknowledgement of a necessary flexible approach toward the implementation of ePI across European countries. European community pharmacists are committed to contributing to an appropriate and timely implementation of ePI in their practice.

When implementing ePI, EMA and national competent authorities should also ensure that pragmatic solutions will be in place to address the potential issue of

outdated paper PILs compared to updated ePI's. The paper package leaflet or primary packaging could for instance include a statement directing citizens to the most up-to-date version of the PIL available electronically.

Additionally, when it comes to liability, the introduction of ePI opens new questions that need to be clarified.

Multilingual ePI

The ePI offers a unique opportunity to meet special patients' needs, including multi-lingual choice options. We encourage national competent authorities to consider linkage to all available EU language versions (as well as Norwegian and Icelandic) of the ePI on their websites, so that European citizens can at all time access the ePI in their language of choice in the community and country of presence.

Given that 80% of marketing authorisations are national ones, it could also be explored to have a user-friendly pan-European database of patient information leaflets / summaries of product characteristics translated into national languages. The paper package leaflet or primary packaging could consequently include a statement directing to the electronic product information available in other EU languages.

Interoperability with EU and global initiatives

PGEU welcomes the focus on interoperability with existing EU and global initiatives in the implementation of ePI in Europe as a measure to ensure a pragmatic implementation process and harmonised access for patients and healthcare providers across the EU.

In the implementation process of any digital technology in healthcare, we would like to stress the need for early involvement of experienced end-users such as community pharmacists to ensure endorsement, support and commitment of all users involved.

Community Pharmacists as Key Trusted Information Sources on Medicines

The need to complement patient information leaflets

Patient information leaflets (PIL) remain a key information source for patients on medicines, despite ongoing criticism about their usability. Since 2005, action has been taken to improve them, with the impact of EU legislation (Directive 2004/27/EC) requiring that they "reflect the results of consultations with target patient groups to ensure [they are] legible, clear and easy to use".

The European Commission PIL-S study[6] found that patients' comprehension of the PIL and its readability can still be improved. The language used is often too complex and the design and layout are not always user-friendly. It pointed out that especially information about interactions, contraindications, dosage instructions and side effects is complex and there is a lack of beneficial information to be found in the PIL in order for patients to make a balanced, informed decision.

The role of community pharmacists in the provision of information on medicines

As the experts in medicines, the most accessible group of healthcare professionals in Europe and often the last professionals that patients see before taking their medication, community pharmacists are profoundly implicated in translating complex information about the use, benefits and risks of medicines to patients in an understandable and balanced manner, with the ultimate aim to improve patients' knowledge about the medicines and therefore adherence to the treatment.

Additionally, no appointment or co-payment is needed to consult a pharmacist for information on medicines and pharmacies can be accessed 24/7, all year round with extended opening hours and on-call services. As such, community pharmacists are excellently placed to provide support for people taking medicines. It has also been demonstrated that pharmacists are, together with the PIL and information received from doctors, the main trusted source of information on medicines for patients.

Moreover, the correct interpretation of product information on possible interactions with other medicines on the paper package leaflet is not easy to do without a pharmaceutical/medical background assessing clinical relevance of the interactions. Pharmacists across Europe review medications that their patients are taking as part of the dispensing process by checking that the medication, dose, strength, and form are suitable for each individual patient. Pharmacies maintain secure and confidential medication records of medicines taken by their patients and thus are also able to check for clinically relevant potential interactions between existing medications (prescription, non-prescription, herbal, etc) as well as check for potential allergies or intolerances (such as for foods, specific medicines, or excipients).

Pharmacy education and training

In Europe, pharmacists must complete a minimum of five years of education and training to become a pharmacist. Throughout this period of training and education, pharmacy students cover all stages of a medicine's lifecycle from initial discovery and development to post-marketing surveillance and pharmacovigilance. Pharmacists are exposed to a unique mix of disciplines during their education and training including scientific, regulatory and clinical elements.

Additionally, the European Directive on the recognition of professional qualifications [7] includes several activities which pharmacists perform in practice.

Specifically, pharmacists:

Provide information and advice on medicinal products, including their appropriate use;

Report adverse reactions of pharmaceutical products to competent authorities;

Provide personalised support for patients taking medication.

Pharmacy services supporting patients' correct use of medicines

At the heart of the pharmacists' day-to-day mission lies their commitment to the safe, effective, and rational use of medicines. This ensures that the right patient receives the right medicine at the right time, with the right dosage, along with the appropriate advice.

Across Europe, several professional pharmacy services are available to patients which aim specifically at improving therapy adherence and reducing medication errors through patient empowerment. These can be particularly useful for poly-medicated patients who are on complex, chronic therapies or other special patient population groups.

An example of a successful and effective intervention to optimise patient outcomes is the community pharmacist-conducted medication review[8] [9] [10] [11]. From the patients' perspective, this review improves their knowledge of their treatment and provides them with an opportunity to address any concerns about the medication. From the pharmacists' perspective, it allows them to provide patients with information on preventing, reporting and mitigating adverse drug reactions (ADRs) and thus increasing adherence to treatment. This consequently improves both clinical and cost effectiveness, reduces medication waste and promotes a more sustainable health system.

A "New Medicine Service" (NMS)[12] provides support for patients who have been newly prescribed a medicine for a long-term condition to improve adherence. This service, provided by pharmacists in eleven EU countries, is initially focused on specific conditions or medications / classes such as those receiving medication for cardiovascular disease, diabetes, hypertension, asthma and anticoagulation or antiplatelet therapy.

Patients are recruited at the point of dispensing, counselled on relevant points about the medication and provide consent for the service. Within several weeks, a consultation between the pharmacist and patient takes place where the pharmacist conducts a semi-structured interview to identify any problems, ADRs, concerns or non-adherence to the new medication. At this point, referral can be made to the patient's doctor, if required, or appropriate advice is provided by the pharmacist and a date arranged for a final consultation within the next few weeks. These consultations are also an opportunity for the pharmacist to provide dietary and healthy lifestyle advice to the patient. In the case of the NMS in England, it has been to be proven cost effective and to improve adherence by 10%[13].

Community pharmacists are also the primary source of advice of medicines available without prescription ('over-the-counter' medicines) and provide advice on common and self-limiting ailments such as coughs and colds, paink, skin conditions and digestive problems. They offer a broad spectrum of services to help patients tackle obesity (weight management programmes), smoking, alcohol consumption and other substance misuse, including medicinal products. They are also excellently located to promote safe sexual health and family planning, including dispensing emergency hormonal contraception. Community pharmacists therefore play an essential role in health education and in ensuring effective and safe self-care.

Increasingly, there is a service-based approach developed for the support of responsible self-care and the provision of advice for treatment and referral of common ailments. For instance, in Scotland, pharmacists have been empowered in this role during the COVID-19 pandemic through the extension of the Minor Ailment Service and increased access to Emergency Care Summary Data[14]. The NHS Pharmacy First Service allows community pharmacies to give people expert help for treating conditions such as sore throats, earache, and cold sores, along with common clinical conditions such as Urinary Tract Infections. Pharmacy teams will offer advice, treatment, or referral to other healthcare teams if required.

It has been demonstrated that pharmacists are, together with the PIL and information received from doctors, the main trusted source of information on medicines for patients:

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Annex: Best Practices From Pharmacists

Community pharmacy organisations across Europe have already taken several initiatives to improve the information sharing on medicines, also beyond the consultation in the pharmacy.

France: Shared Pharmaceutical Record - Dossier Pharmaceutique (DP) -Patient

An ongoing project called DP-Patient aims at giving patients direct access to their medication record (DP), a nationwide health solution operated by the French Chamber of Pharmacists pursuant to the Public Health Law. In France, every patient that wishes to gets a DP (Dossier pharmaceutique), a record of all medicines dispensed to them within the last four months, accessible to any community pharmacy and increasingly hospitals treating them. New tools are being developed to allow direct access to that record, along with several related services and information (adherence, nearby pharmacies, relevant batch recalls, etc.).

The Netherlands: Apotheek.nl medicines information website

The Royal Dutch Pharmacists Association (KNMP) makes comprehensive medicine information available for everyone on their public website www. apotheek.nl. This website provides easily accessible and easy to understand information on medicines. Apotheek.nl has been awarded the best medicine website in the Netherlands three times in a row and has over 1,5 million visitors per month. In addition to offering comprehensible text information for over 1600 medicines, the website also includes more than 40 instruction videos in 4 languages (Dutch, English, Turkish, Arabic) on medicine use, for example, the use of inhalers or applying eye drops. Moreover, the website offers several tools to meet specific patients' needs such as those with impaired sight and low literacy levels. Apotheek.nl is also available as a webapp.

The information provided is based on the decision support information for medication surveillance by physicians and pharmacists. In this way, pharmacists and patients have access to complementary drug information from the same source. However, it is stated that this online medicine information should always be used as a complement to the consultation with the pharmacist and the package leaflet. Recently, the KNMP has together with the Dutch medicines' agency CBG-MEB, made a new short form of the package leaflet: 'Medicine in brief[15]. It contains the most important information patients need to know about their medicine in one A4 leaflet and is promoted as a supplement to the full paper package leaflet.

Portugal: Med 180º Project

The Med 180º Program is designed to give patients the information they need regarding their medicines. This program promotes adherence and the correct, effective and safe use of medicines and health products, through several communication channels, according to the preferences of each user (posology/dosage labels, SMS, e-mail, app). Another very important role of this program is strengthening the role of pharmacies as gatekeepers for medicines' safety and facilitate patient's dosage management.

This program, available in community pharmacies since March 2018, constitutes an added value service, for all patients, in all the dispensing services, reinforcing their relationship with their pharmacy.

The pharmacists identifies a patient as a potential beneficiary of this system, that manages to inform him with customise notifications regarding his specific medication.

This program its a tool to better inform patients, by positioning community pharmacies in a new level of interaction with their patients in terms of posology management.

With this program, pharmacies are able to use several tools, as the Famácias Portuguesas' APP, text messages, email, labels or tickets to keep patients updated on their posology.

This system allows to use the best communication channel according with
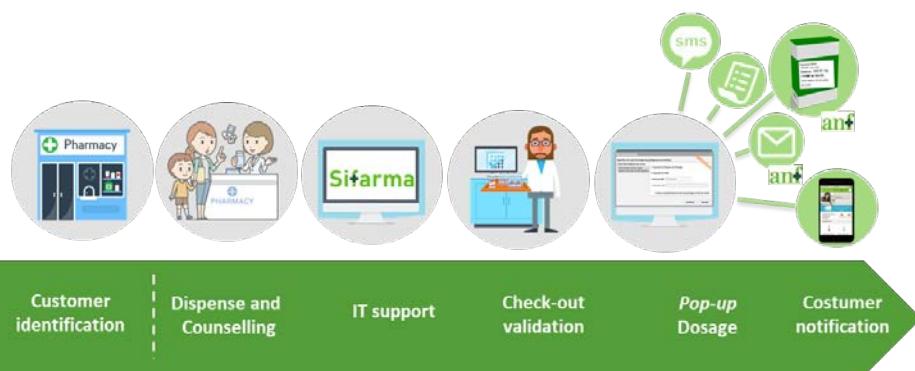
people's needs and their literacy levels regarding digital tools. In the case of older patients or patients that have increased difficulties in using digital tools, the pharmacist can adapt the information to a label or ticket so that patients can easily access this information. As we live in as era of constant technological transformation, this program increases value proposition and differentiation of pharmacies, through technology, without leaving the elderly or the more digitally challenged behind.

Until December 2020, 90.3% of the Portuguese pharmacies had this service activated and were using it.

Spain: Bot PLUS, Medicamento Accesible PLUS and Tú Farmacéutico Informa

The General Pharmaceutical Council of Spain database, BOT PLUS, offers free access to patients through the provision of updated and semi-structured information of product information. BOT PLUS makes available to all users the product information leaflet (PILs) of medicines and leaves an open space so that patients can consult how to take their medicines properly or what precautions they must take into account. In addition, the database provides information about the administration of medicines in population under 18 (for example for parents) and during pregnancy or breastfeeding in accordance with PIL recommendations. This information is also easily visible through pictograms and warning messages that help patients to get a better understanding of the appropriate use of their medicines.

Recently, thanks to the close collaboration between the Spanish Agency of Medicines and Medical devices (AEMPS), BOT PLUS has included images of medicines, both the image of the packaging and the pharmaceutical form itself.

In addition, the General Pharmaceutical Councill has worked in the construction of a form-shape browser to help community pharmacists and patients to identify their tablets or capsules following their form, colour, presence of score or inscriptions.


Medicamento Accesible PLUS

Medicamento Accesible Plus is a free app promoted by the General Pharmaceutical Council of Spain, ONCE Foundation (Spanish organisation for blind or visually impaired people) and Vodafone Foundation. It enables easy and electronic access to product information leaflet (PILs) for patients and carers to consult information on medicines in a user-friendly way and to facilitate their understanding of adherence to treatments.

In its beginnings, the app started out for blind people and those with impaired sight, but later on it was extended to the elderly and people with mobility difficulties. Thus, the app follows the principle of easy design and accessibility without leaving no vulnerable person behind.

Medicamento Accesible Plus offers a wide range of advantages. For example, it can be customised according to the health situation of the patient (pregnancy, breastfeeding, intolerance to excipients, swallowing difficulties). When an incompatibility is detected between the patient's condition and the medicine, the app issues personal alerts to warn the patient. The application also allows the user to be aware of the expiry date of the medicines stored.

The application works into two ways. On one hand, the user can take a picture of the barcode or Data Matrix code in the medicines packaging. Then, he/she will be redirected conveniently to the PIL for that medicine. On the other hand, the patient can also search by name or code of the medicine. Once on the monograph for that medicine, the patient can visualize/listen to the different sections.
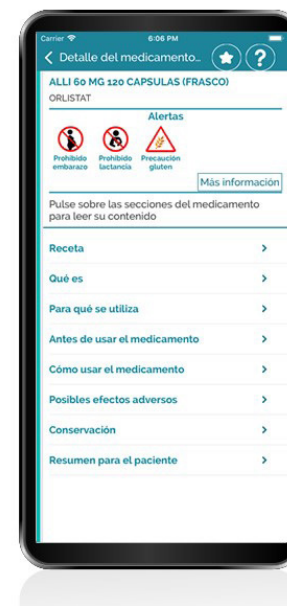
Tu Farmacéutico Informa

The Youtube channel 'TuFarmacéuticoInforma' from the General Pharmaceutical Council of Spain is an online support resource aiming at providing patients quick and reliable information of medicines, medical devices (such as orthopedic products) or medicinal herbs. Pharmacists give health advice to a broad audience as to how to make a responsible use of medicines and products and how patients should take their medications properly according to the SmPC and PIL.

TuFarmacéuticoInforma has around 234,000 subscribers and has become a health reference for patients in these last 5 years in Spain and Latin America, with more than 38 million views and an average viewing time of more than 60% for each video advice.
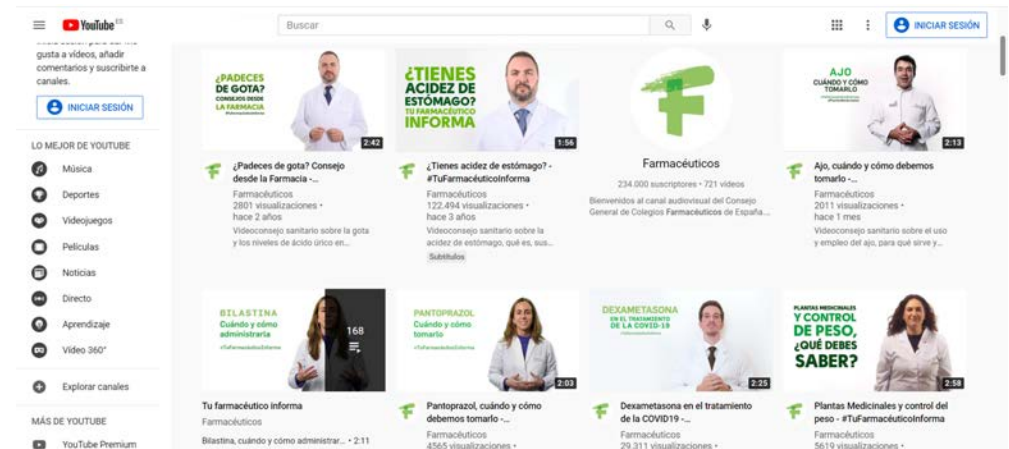
During the months of total lockdown due to the COVID-19 pandemic, the videos have been of vital importance by focusing on providing information on the correct use of masks, avoiding the spread of COVID-19 hoaxes and promoting the rational use of medicines from the patients' home.

Sweden: PIL and other information on websites and in apps with possibility to personalise

Most Swedish pharmacies have their own websites. It is possible to search for any medicine at the websites and to get information about the product. The Product Information Leaflet is normally available in an electronic format through a link or embedded in the user interface. The information is always updated to the latest approved version. Many pharmacies also offer services through apps.

Nearly all prescription are e-prescriptions and the patient can access the information about their prescriptions by logging in to the pharmacy web sites via BankID, an electronic identification system in Sweden. After logging in the patient can access the ePI/PIL for every prescription. In that way the patient gets a personalized set of ePI's based on his/her medication.

Apoteket AB also offers additional advices for most medicines in the prescription list after logging in to their site or app. These advices are for example recommendation to take the medicine with or without food, if the medicine have to be swallowed whole and if there are any certain storage conditions. These advices are a selection of the information that is presented to the pharmacists in their IT-system when dispensing a prescription. The information/advice is also often accompanied by a symbol or pictogram.

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