E-labelling and digital transformation in pharmacy

Report from a FIP insight board

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Colophon

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Acknowledgements

Introduction

The International Pharmaceutical Federation (FIP) launched its 21 Development Goals (DGs) in 2020 as a key resource for transforming the pharmacy profession globally, regionally and nationally. FIP DG 10 (Equity and equality) aims to address equal accessibility of patients and populations to various services. This includes access to digital health services, also highlighted by FIP DG 20 (Digital health). As the world is rapidly evolving, technology follows to simplify daily tasks and challenges. The World Health Organization (WHO) stated that digital technologies are now integral to daily life and their use can accelerate the global attainment of health and well-being.[1]

The pharmacy profession has embraced digital technologies across all levels of pharmaceutical care services. The [FIP Statement of Policy on Digital Health](#) highlights the benefits to the pharmacy profession from the utilisation of digital tools in addressing healthcare challenges and improving access to patients' needs, resulting in improved health outcomes and reduced costs of healthcare.[2,3] Pharmacists have contributed to improving digital health through the implementation of online pharmacies, e-prescribing, e-dispensing, shared electronic health patient records, decision support tools, telehealth, online presence of community pharmacies, online counselling, chatbots and remote patient adherence monitoring.

The current approach to providing patient information leaflets (PILs) with over-the-counter (OTC) products brings challenges as consumers often find the information irrelevant or not tailored to their needs. Current approaches in the use of PILs suggests that the information may not always be relevant, not tailored to patient's needs, not formulated to address patients' specific questions and may have adverse environmental impact. Studies show that majority of the respondents (52%) in recent studies occasionally read the patient information leaflet, 37% always read it, and 11% never read it.[4] PILs could be seen as an inappropriate use resource with environmental repercussions, while, at the same time, falling short of their core purpose, which is to provide comprehensible information enabling individuals to effectively manage their health. For that reason, it is important that pharmacy finds alternative systems that will improve consumer health literacy, make available relevant updated, easily usable patient information and at the same time help contribute to a sustainable environmental future. Alternative approaches, such as e-labelling, have been explored in some regions.

E-labelling, such as using QR codes, could offer many benefits, some of which include improving environmental sustainability and improving consumer health literacy through access to trustworthy and relevant information. It could also allow for customising information, whether in terms of content or delivery, such as utilising audio formats for individuals with visual impairments. This could in return improve self-care and lead to better allocation of resources where they are most needed, supporting the sustainability of the overall healthcare system.

Alongside the benefits e-labelling brings, several challenges include potential exclusion and inequity for those who cannot access digital systems for many reasons. It also relies on digital platforms and possibly the internet for access to health information, potentially exacerbating the existing inequities due to disparities in access to both. In addition, participants discussed privacy and security concerns, the complexity of the transitioning process from paper leaflets, regulatory challenges, and the possible challenges with regard to patient health and digital literacy.

At the 81st FIP World Congress of Pharmacy and Pharmaceutical Sciences in Brisbane, Australia, which took place in September 2023, pharmacists from around the world joined an insight board hosted by FIP for a discussion and insight gathering on the advantages and disadvantages of e-labelling as well as the impact it can have on pharmacy and the equity of healthcare services.

The experts at the insight board addressed the following questions:

1. What is the value/purpose of e-labelling?
2. What are some of the barriers to e-labelling (in your region/country)?
3. What roles does pharmacy play now and, in the future, concerning e-labelling? How can the pharmacy profession take ownership of e-labelling, given its unique role between patients and regulators?
4. Can e-labelling serve as a means to bridge inequitable access to medicines information? If so, what prerequisites must be in place for e-labelling to achieve environmental sustainability, increased access to medicines, and enhanced health literacy?

This report provides a summary of the insight board discussion as well as the key insights that were shared. It should be noted that the views expressed during the insight board are those of the individuals based on their extensive expertise

and experience. They do not represent FIP policy or positions, although they may build on existing positions and statements.

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1 The value and purpose of e-labelling

Participants discussed the value and purpose of e-labelling, including the benefits of exchanging a physical paper leaflet for a digital one. Several themes emerged from this discussion:

1.1 Environmental and economic sustainability

One of the greatest values of e-labelling is its positive impact on the environment. E-labelling eliminates the need for the pharmaceutical industry to print patient information leaflets (PILs), which are often packaged with medicines. Reducing the demand for paper, ink, electricity and other resources associated with printing can significantly reduce the impact of the pharmaceutical industry on the environment. In addition, e-labelling eliminates the need for the shipping and physical distribution of PILs, reducing the carbon footprint associated with them.

In addition, over the long term, e-labelling can lead to lower economic expenditure for pharmaceutical companies and healthcare facilities by reducing the need for printing, packaging and distributing traditional PILs. Additionally, it can reduce the administrative burden of managing physical materials such as the waste disposal of PILs.

1.2 Access to medicines information

It is essential that patients can access their information in an easy and equitable way. Participants reported that e-labelling is considered a feasible approach for patients to access medicine information, allowing them to easily obtain their data through the digital tools designed efficiently to facilitate accessing the required information.

> "E-labelling is a good way of having a new form of communication in which content can be more user-friendly and clearer."

E-labelling plays a significant role in providing patient-centred care by tailoring information and resources to needs and preferences of individual patients. It allows patients to access information in a preferred language and format, such as text, audio, or video, making patient information accessible to different audiences. Therefore, patients with different learning preferences, disabilities, or literacy levels can all access the information in the way they prefer. It also ensures consistent access to information as opposed to a PIL that could be lost or misplaced.

> "Elderly people's [perspective] of PILs is that [they are] hard to read as the print font size is very small. If provided electronically, they can get an e-reader or voice-to-text option to allow easier access to information."

> "In some countries, like India, there are a lot of languages, and it is not easy to print a leaflet in several languages."

In addition, e-labelling platforms often include search functions, enabling patients to quickly find specific information they need, such as dosage instructions or potential side effects. This feature enhances the accessibility of relevant content.

> "E-labelling is not so daunting for the patient. It makes it easier for the patient to look up the information. It can be an extra tool to help the pharmaceutical practice."

E-labelling also allows for the immediate access to up-to-date information, ensuring patients always have the most current data on their medicines. This feature is particularly crucial when there are changes in dosages, administration guidelines or safety information.

1.3 Medicines information delivery

PILs are crucial for patients to access medicines information, but they often contain content aimed at healthcare professionals and the pharmaceutical industry, making them less user-friendly and useful for patients.

> "In the PIL so much of the information is about the pharmacy industry protecting itself not just what the patient wants."

> "Doctors in the past days did not have easy access to information, so the leaflet actually is oriented toward the doctor. Now, it is easy for doctors to get access to information."

> "The leaflet contains a lot of detailed and scientific information only read by doctors but not by the patients."

During discussions, it was suggested that e-labelling can cater to both patients and healthcare providers. An Australian example showed how different packages were used to convey information to doctors and patients, highlighting the potential of e-labelling in this regard.

> "In Australia, there are different packages depending on whom [the information] is oriented; technical details to the doctor or more easy informative for patients."

In today's digital era, healthcare providers have easier access to detailed medical data, while e-labelling offers patients user-friendly information that does not depend on their health literacy level (not considering digital literacy). Participants discussed the integration of artificial intelligence (AI) into e-labelling systems and how it holds the potential to further enhance user experience by personalising information delivery, offering predictive insights, and ensuring dynamic adaptation to individual patient needs. This technological synergy could contribute significantly to the efficiency and effectiveness of e-labelling platforms in healthcare.

1.4 Medication adherence

Some e-labelling platforms enable patients to set medication reminders and provide tracking tools. These features help patients adhere to their treatment regimens, which is crucial for successful healthcare outcomes. Participants have discussed how e-labelling can also lead to better communication between a pharmacist and a patient, potentially contributing to a culture of patient empowerment and informed decision-making as individuals become more actively engaged in understanding and managing their healthcare.

E-labelling, therefore, ensures that patients receive the right information precisely when they need it. This not only supports informed decision-making and improved adherence but also fosters a trusting and collaborative relationship between patients and healthcare providers, ultimately leading to better medication adherence and better healthcare outcomes.

> "E-labelling involves ensuring that patients receive the right information when it's most relevant in their healthcare journey. This includes aligning the information provided in e-labelling with thestages of the patient's treatment and allowing for more tailored and relevant exchanges of information."

2 Barriers to e-labelling

Experts at the insight board discussed the barriers to e-labelling in their regions and countries and why it cannot be implemented immediately, including barriers to the transition from PILs to e-labelling or with e-labelling itself. Numerous themes emerged from the discussion.

2.1 Digital literacy and access disparities

E-labels are delivered through electronic means like QR codes, barcodes or URLs, which rely on technology and the internet. Therefore, one of the biggest barriers to e-labelling is the varying accessibility that the population have to smart devices or the internet.

> "E-labelling can be restricting to patient groups, making heath more inequitable and less accessible."

> "Inequity may be worsened if there is an immediate shift to the e-label. Those who are most in need may not have access to such technology."

E-labelling assumes that patients not only have access to digital devices but are also digitally literate. For example, many older adults face specific challenges when using digital technology and can therefore be unable to use e-labels effectively. Consequently, if these patients with limited or no access to internet or smart devices, or even the knowledge to use either, were unable to use e-labels, they might need to go back to the pharmacy to request the information they need, making e-labels a barrier to equitable access to health information.

> "It is the right of the patient to have access to a leaflet or an e-leaflet even in the absence of internet access, and it is the responsibility of pharmacists to guarantee this."

> "There is the elderly population who may have no access to the internet. If they want to know more about their medicine, they may need to go to the pharmacy."

2.2 Privacy and security concerns

E-labelling systems can handle sensitive health information, raising concerns about data security and privacy breaches. There is a risk of personal information being accessed or shared without patient consent if platforms are not properly secured.

> "E-labelling poses an issue with data protection."

Additionally, there is the issue of data ownership and understanding who owns patient information and who regulates access to it. Therefore, it must be ensured that all these platforms comply with laws and regulations associated with patient privacy, which could probably add another barrier to transitioning from PILs to e-labels.

2.3 Transition, implementation and complexity

Participants discussed not only the barriers of e-labelling, but also the process of transitioning from PILs to e-labels.

> "Is the concern in the transition from PIL to e-label or is it the e-label itself?"

The transition to and implementation of e-labelling involves several measures that require careful consideration. During the discussion, it was noted that the system must be designed with a focus on functionality to ensure that patients can safely and effectively access their information.

> "We need to think about the requirements to transition to e-labelling first. Barriers could includethe training required as well as health system integration."

Participants emphasised that those responsible for creating packages and inserts, as well as healthcare providers, must receive retraining to guarantee the delivery of effective health information to patients.

> "The issue is [that] we have to retrain people who are doing the package inserts to produce better models."

Not all patients may perceive e-labels as a convenient alternative to PILs. Participants described e-labels as a double-edged sword due to the complexity and the depth of information they contain, which may potentially misguide and confuse patients. Moreover, patients might be presented with extraneous details concerning their medication, encompassing all potential adverse effects, potentially acting as a barrier to medication adherence.

> "Information could be very long, very specific and not easy to understand. It becomes dangerous in two ways — patients misunderstanding the information given, eventually leading to misapplication of medication instructions and patients fearing the side effects leading to decreased adherence to treatment."

2.4 Regulation of e-labels

During the discussion, it was noted that having various formats may hinder patients' effective access to their information. Participants discussed the need for an approved format to simplify and enhance the process of accessing the information, thereby promoting optimal healthcare outcomes. Ensuring that these digital platforms comply with laws and regulations governing the healthcare and pharmaceutical industries is essential, and this may be difficult with the differing laws and regulations among countries and regions.

> "We may face an issue with the regulations behind changing leaflets. Everything about e-labelling needs to be regulated."

It is important for pharmaceutical companies, healthcare providers and e-labelling developers to work in close collaboration with regulatory bodies to ensure that e-labelling platforms are fully compliant with all relevant regulations. Non-compliance can result in legal and financial consequences, as well as damage to patient trust and safety.

2.5 Impact on pharmacy and pharmacists

Pharmacists play a crucial role in the community that goes beyond simply dispensing medicines, as they can provide effective healthcare to patients by educating them and supplying them with information about their medicines and their use. Therefore, with the emergence of e-labelling, pharmacists will have to ensure that patients can adequately utilise it through educating their patients and training them on how to use e-labels. The participants in the insight board highlighted that e-labelling could potentially add to the workload of pharmacists.

> "Increasing health literacy may also require printing leaflets. Practitioners from community pharmacy may feel the need to print the leaflet and then get reimbursed for it."

In addition, participants discussed the potential of e-labelling in displacing pharmacists from their traditional role as well as in increasing competition among health practitioners.

> "Will practitioners' work be replaced by the e-label?"

3 The role of pharmacy

The third area that the participants discussed at the insight board was the role that pharmacists and the pharmacy profession can play in e-labelling.

3.1 Patient education and guidance

During the insight board, participants explored the involvement of pharmacies and pharmacists in the shift from PILs to e-labels. They delved into the ways pharmacists can take ownership in the process, aiming for a smooth and efficient transition.

Pharmacists' unique position allows them to serve as a bridge between regulatory authorities and patients, ensuring that the transition to e-labelling is not only legally compliant but also patient-centred. Their unique position allows them to advocate for the needs and concerns of patients while facilitating a smooth and successful implementation of e-labelling in the pharmacy setting.

When interacting with their patients, and as with educating patients on their medicines and medication regimens, pharmacists will have to educate and train patients to use e-labels efficiently to access health information. This involves explaining how to access e-labels, interpret medicines information, and use any interactive features available. The role of pharmacists in this case includes tailoring the approach they use with their patients to match the patients' health as well as digital literacy levels.

> "If patients with lower health literacy look at the e-label and don't know how to use it,
> pharmacists will need to navigate it with them to help them understand."

Participants mentioned that the role of the pharmacist will shift towards catering to patient needs based on their literacy, while placing patient safety at the highest priority.

> "Patient safety is the most important aspect."

> "The label is between the provider and the patient, so the pharmacist has to evolve and lead
> thechange to e-labels, focusing on the safety of the patient."

3.2 Empowerment of pharmacists and collaborations with other stakeholders

Participants at the insight board mentioned that e-labelling can empower pharmacists as they are the most accessible healthcare providers to patients. As mentioned above, they are the bridge between the patient and health information. Their role can extend beyond mere information provision to encompass personalised guidance, health promotion and a vital link in the overall healthcare.

Pharmacists can therefore be empowered to engage in the development of tools and resources that enhance efficiency, improve patient education and streamline patient communication. The integration of technology not only facilitates daily tasks but also allows pharmacists to elevate the quality of patient care and stay at the forefront of healthcare advancements.

> "Pharmacists have the opportunity to shape e-labelling."

In addition, pharmacists working across diverse fields can collaborate with various stakeholders involved in e-labelling. This collaboration extends beyond facilitating a seamless transition to e-labelling; it also involves actively contributing insights to enhance the effectiveness and user experience of e-labelling in different capacities. Through this collaborative effort, pharmacists can play a vital role in shaping the evolution of e-labelling systems, ensuring that they

align with the specific needs of their respective fields and contribute to advancements in healthcare information dissemination.

> "Pharmacists working in different fields within the pharmacy field like regulatory and development can be involved in pilot projects on e-labelling."

For instance, pharmacists have access to more patient feedback/behaviour and user-experience insights that can enhance e-labelling and access to health information. They can work with other stakeholders to identify and fill information gaps that will in return streamline the transition from PILs to e-labels.

Participants mentioned that pharmacists should therefore be involved in the policy setting and decision-making processes around e-labels as they could bring a wealth of practical knowledge, patient-centred perspectives and regulatory expertise to the table.

> "There is a regulatory framework that needs to be taken into consideration and we [pharmacists]have to go in it."

> "Pharmacists should be involved in creating these [e-labelling] policies and setting the appropriate framework in which pharmacists' voices can be heard."

> "Pharmacists can contribute to discussions around the role of different organisations and companies in enhancing patient communication and supporting patients to get the best carepossible."

Similarly, pharmacists can also collaborate with drug manufacturers through patient research to provide the most suitable template providing patient information through e-labels that are not only informative and compliant but also responsive to the diverse needs of patient.

> "Involving pharmacists in discussions about what information should be in the e-label and what shouldn't as well as which health providers are better to serve as patient counsellors is important."

Finally, pharmacists can contribute to educational initiatives aimed at improving patient health literacy regarding e-labelling. By offering guidance on how to effectively use digital resources, pharmacists empower patients to derive maximum benefit from e-labelling platforms.

4 The impact of e-labelling on equity and access

During the insight board, participants discussed the ways in which e-labels can improve equity and access to health and health information, and several factors were highlighted.

Participants emphasised the impact of e-labels on information accessibility, enabling patients to retrieve information in their preferred format or language. This has the potential to enhance equity and accessibility in terms of medicines information, potentially advancing patient health literacy and empowering them to better manage their health. Participants further proposed an extension of this approach, suggesting the possibility of direct communication with patients through SMS messaging or chatbots, facilitating improved patient engagement. In addition, participants mentioned how e-labelling can be one way to improve patient health and digital literacy, eventually leading to better health outcomes through patient empowerment. Consistent access to up-to-date information also allows patients to stay on track with their health regimens, leading to better equity in health.

One participant provided an example of the mandatory use of a mobile application to monitor and document COVID-19 cases throughout Malaysia during the pandemic. This compulsory measure led to the fast learning of technological proficiency by the Malaysian population within a short timeframe. This instance highlights the practicality and potential viability of introducing e-labelling into a healthcare system.

Participants also discussed the potential of using the resources and financial investments allocated to paper leaflets towards other sectors within healthcare. Reallocating these funds to foster improvements in health services, with the ultimate goal of advancing health equity can be beneficial for creating a more equitable healthcare landscape.

On the other hand, participants highlighted the potential of e-labelling to exacerbate inequalities, particularly across age groups and in socioeconomically disadvantaged communities. Not everyone has internet access or the necessary technology to utilise e-labels, and the younger demographic may find them more user-friendly than the older population. Therefore, e-labels have the potential to either minimise or exacerbate the pre-existing inequities with a healthcare system.

5 Conclusions

In conclusion, the insight board discussions highlighted the potential benefits and challenges of e-labelling in healthcare.

Benefits include:

- Environmental sustainability;
- Access to medicines information;
- Patient-centred care;
- Medication adherence; and
- Economic sustainability.

Challenges include:

- Disparities in access to information;
- Privacy and security challenges;
- Transition and implementation barriers;
- Regulatory hurdles; and
- Impact on pharmacists.

The impact of e-labelling on pharmacists and pharmacy includes pharmacists taking bigger roles in patient education and guidance, and empowerment and collaboration with other stakeholders involved.

Participants also discussed the potential positive and negative impacts of e-labelling on equity and access. The positive effects include improved information accessibility, patient empowerment and streamlined communication, whereas several disadvantages were highlighted, including the potential to exacerbate existing inequalities, especially with regard to digital access.

In summary, while e-labelling offers transformative possibilities, addressing barriers and ensuring a collaborative, regulated approach is crucial for attaining its full potential in healthcare. FIP will consider the development of guidance on e-labelling that takes account of all the elements in this report for ease of use in practice.

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