

Electronic product information (ePI)

Securing the future for accessible delivery of medicine information through digitalisation

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About this report

This report was written by Stefano Spalvieri and Suzanne Wait at The Health Policy Partnership.

It explores the potential benefits of transitioning to electronic product information (ePI) for patients, healthcare professionals and overall health system efficiency. It aims to serve as a helpful guide for policymakers to ensure this transition can optimise ePI's potential as a core feature of digital-first, equitable health systems.

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- **Prof. Dipak Kalra, President, European Institute for Innovation through Health Data, Gent, Belgium**
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Executive summary

Providing people with accurate, up-to-date and comprehensive information about their medicines is critical, but paper-based information has several shortcomings. Research suggests the information contained in current product information is often considered unclear and inaccessible, and it is poorly suited to meet the needs of people with low literacy or certain disabilities.¹

Transitioning to electronic product information (ePI), where information about medicines is presented on a digital platform, offers the opportunity to make medicine information more accessible and tailored to the needs of each person. Enhanced forms of ePI can contain videos, filters and other tools to make the information easier to read and digest, as well as more personalised and accurate. This can help people improve their confidence in and understanding of their treatment and feel empowered in relation to their health; it can also potentially enhance their adherence to prescribed medication. When fully integrated into other digital platforms, enhanced forms of ePI have the potential to overcome many of the historical limitations to information on medicines for patients.

A transition to ePI will also help improve the efficiency of medicine development, making it more environmentally sustainable. The development of product information is a costly and protracted process with a high carbon footprint.² Product information needs to be reprinted every time there is a product update, and information often needs to be available in multiple languages, culminating in a significant use of water and paper. Transitioning to a digital-first solution would bypass this resource use, improving efficiency in medicine supply chains. The streamlining and improved efficiency in supply chains would, in turn, translate into clear cost savings as well as benefits for patients and the environment.³

As ePI evolves, it will be essential to engage patient communities and people at risk of digital exclusion in its development. Co-design will be crucial at every step of development to ensure that everyone – regardless of ability, digital literacy and socioeconomic position – can fully benefit from ePI, and that it makes the most of available innovations in digital accessibility. Close collaboration between developers of ePI, regulatory bodies, governments, healthcare professionals and patient organisations will also be key to ensuring an efficient and inclusive transition to ePI, fully integrating it into digital-first health systems.

1. Information on medicines: an essential component of good patient care

Providing people with accurate, up-to-date and comprehensive information about their medicines is integral to patient safety. Appropriate medicine information is crucial at all stages of care, and is equally important for people taking medicines, healthcare professionals prescribing them and pharmacists dispensing them. Product information traditionally includes a patient information leaflet for the person taking the medicine, a summary of product characteristics (SmPC) for healthcare professionals and labelling (information on the outside of the package).⁴

⁵ The patient information leaflet includes advice about what the medicine is made from and its intended purposes, as well as any known contraindications or possible side effects.⁶

Product information has traditionally been provided in paper-based information leaflets, but evidence suggests that these often fail to meet people's needs for clear, accessible information.

Data from the US suggest that fewer than 50% of people who take medicines containing product information read it.⁷ In the UK, a study has found that over 25% of people taking medicines did not read the paper information leaflets, for reasons that included the information being too technical or difficult to understand.¹ Of those who did read the information, 10% did not understand it and 55% wanted to know more.¹

There are also equity issues with current product information, as it is not adapted to the wide range of literacy and reading abilities throughout society.⁸ In the US, 36% of people have limited health literacy; of these, 14% have below-basic health literacy.⁹ A 2015 study in England found that 43% of participants had inadequate comprehension of health information text.¹⁰ This is a considerable barrier to the use of product information. Paper formats are also not accessible for people who cannot see, and the small font often used is difficult to read for anyone with a visual impairment.¹¹



50%

In the US, fewer than 50% of people who take medicines containing product information read it.⁷



43%

A 2015 study in England found that 43% of people who read information provided with their medicines did not fully understand it.¹⁰

Transitioning to a digital or electronic format for product information may help address many of these limitations and provide a more environmentally sustainable alternative to product information. Electronic product information (ePI) refers to adaptation of the authorised product information for medicines into an electronic format and its dissemination via the web and e-platforms.⁴ Current paper leaflet production generates an estimated 500,000 tonnes of carbon dioxide every year.² A recent analysis found that water consumption for paper prescribing leaflets in the US amounted to almost 11 billion gallons annually, making the process significantly water intensive.¹² ePI offers the potential to transform the way people access information about their medicines and health, overcoming accessibility barriers that exist with paper-based formats. It can support the integration of data across a health system, particularly if it is integrated with other digital advances such as electronic medical records. It may also help streamline the supply chain and medicine packaging, helping countries fulfil their commitments to improving the environmental sustainability of healthcare and optimising efficiency in the development of medicines.

2. ePI: an evolving landscape

Regulatory and legislative changes

Many countries are making regulatory and legislative steps towards allowing electronic formats of medicines information, but they are at different stages in this transition. Some countries are looking to replace all product information with electronic versions, while others are only focusing on replacing the prescribing information such as the SmPC. Additionally, where some countries are discussing legislation to completely replace paper-based information, others are only contemplating ePI as a complementary tool to paper formats. While the pace of change varies considerably between countries, the direction towards digital platforms seems clear and inevitable (Table 1).

Table 1. ePI regulatory landscape in different countries/regions

COUNTRY/REGION	HEALTH AUTHORITY / REGULATORY BODY	REGULATION/LEGISLATION
Australia	Therapeutic Goods Administration (TGA)	With long-standing regulatory support, information on all oral and topical medicinal products is via ePI. ¹³ Australia has made paper product information optional and pharmacists provide support for patients who require a paper format. The use of ePI for prescribing information and product information remains widespread. ¹⁴
Brazil	Brazilian Health Regulatory Agency (ANVISA)	Resolution passed in 2022 approves the use of full ePI via QR codes along with paper product information. ¹⁵ In November 2023, proposed legislation called for centralised ePI databases using structured and interoperable data, paving the way for digital-first solutions.
China	National Medical Products Administration (NMPA)	Legislation for e-labelling is currently in its infancy. However, as of 2024, there is an active ePI pilot programme using QR codes. ¹⁶

cont.

2. ePI: an evolving landscape

EU	European Commission (EC) European Medicines Agency (EMA)	<p>After extensive consultations, the EC's and EMA's position is that ePI refers to providing electronic versions of product information without any changes in content.¹⁷</p> <p>In 2023, draft EU pharmaceutical legislation called for mandatory ePI on all medicines in the EU with the option to remove paper for hospital-administered products. Additionally, it called for the establishment of a central system that would develop an interoperable app to access ePI.</p>
Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	<p>A government-mandated change to replace paper leaflets with ePI was implemented in 2021, with all patient information leaflets being uploaded to the PMDA website.¹⁸</p>
Singapore	Health Sciences Authority (HSA)	<p>In 2021, the HSA approved a full transition to digital formats of product information available via URL or QR codes, dispensing with the need to rely on paper copies.¹⁹</p>
USA	US Food and Drug Administration (FDA)	<p>In 2014, the FDA proposed to amend the requirement that prescribing information be delivered primarily by paper.²⁰ There is political and legislative resistance to this; however, a version of the Bill is currently (December 2023) in the House of Representatives and has been referred to the Subcommittee on Health.²¹</p>

Building towards enhanced digital functionality

The transition to ePI is a gradual process and can best be understood as a continuum, from 'basic' to 'enhanced' ePI. The 'basic' version of ePI refers to the direct translation of the paper-based medicine information into a standard electronic PDF, with no additional features.²² The 'enhanced' form of ePI would include improved accessibility features such as audio description,



The 'enhanced' form of ePI would include improved accessibility features such as audio description, larger text and simpler language, along with 'sort' functions that would change the person's interaction with the information.

larger text and simpler language, along with 'sort' functions that would change the person's interaction with the information. It could also be computable and semantically annotated, meaning the text could be linked to images or graphs, accessed in multiple languages, and tailored to individual people's situations or information needs, such as being pregnant or on multiple medications. It could also be more easily accessible for people with diverse abilities.²² Some of these benefits will also extend to healthcare professionals, enhancing their understanding of the information presented and facilitating communicating that information to their patients.¹⁷ It is important to note that, at present, available versions of ePI are of the 'basic' kind; however, their design is evolving to move towards more enhanced versions and ensure these are in line with regulatory standards.

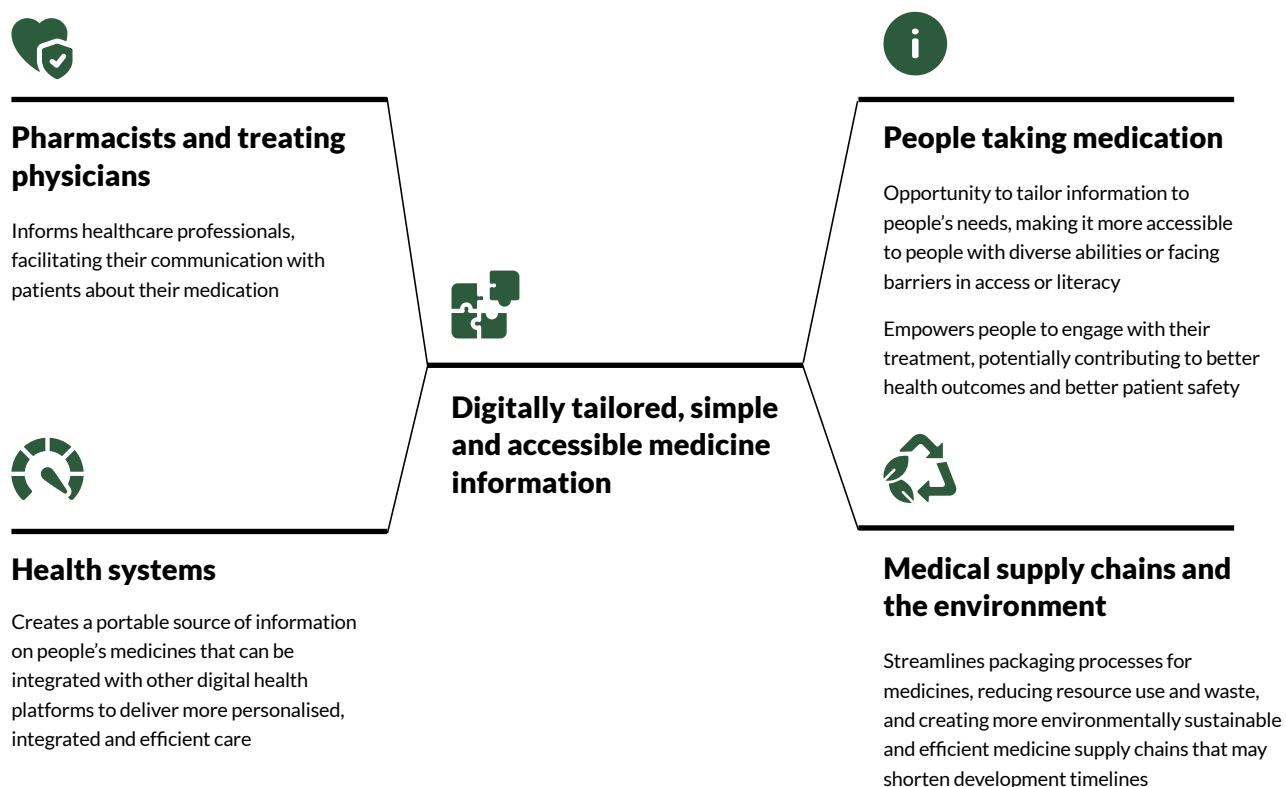
3. What are the potential benefits of ePI?

‘ePI has huge potential and offers important opportunities to overcome problems encountered with traditional product information. However, the policy and legislative discussion needs to address the full scope of its potential use, to ensure that potential is reached.’

Petra Wilson, Health Connect Partners

ePI can bring several benefits to different stakeholders. In addition to benefits to medical supply chains in medicine research and development, ePI can bring benefits for: people taking medication, physicians and pharmacists prescribing and dispensing medication, and health systems overall (Figure 1).

Figure 1. Potential benefits of ePI for people taking medications, healthcare professionals and health systems



Acceptability to users

As a new format for providing information on medicines, ePI must achieve high levels of engagement from users. Though studies so far have been limited by the recent introduction of ePI in many countries, existing data suggest that ePI is both acceptable and satisfactory for a broad range of users. In a prospective cohort study with 112 people with newly diagnosed prostate cancer, the control group was given traditional paper product information, whereas the intervention group was given product information in a paper format and an electronic tablet that contained all the required information plus supplementary videos.²³ The electronic format had a high usage rate and demonstrated comparable patient satisfaction to the paper format.²³ Similarly encouraging results come from a survey of 321 people that investigated attitudes towards switching to electronic formats of leaflets about vaccines.²⁴ Respondents, who included pregnant women, young parents and older people, were happy (77%, 82% and 66% respectively) to receive information electronically rather than in a paper format, especially when given the option to also request a paper version.²⁴

Personalised presentation of information

Particularly in its enhanced forms, ePI has the potential to tailor, target and adapt medicine information to each person's needs and abilities, empowering people in their use of medication. For example, an enhanced format of ePI could include a 'sort' function to allow people to more rapidly access information most relevant to them (e.g. if they are older and on multiple medications). It could offer specific information depending on a person's current use of medication to highlight any risks of contraindications, which is particularly important for people with multiple conditions who may have been prescribed medication by different physicians. This personalisation may ultimately improve outcomes as people experience improved access to information tailored to their needs.

ePI can also make information more accessible for many people with diverse abilities, empowering them with respect to managing their health. Currently, paper-based product information is inaccessible for people who are blind or partially sighted; they have to rely on other people and request alternative formats that are accessible to them (if these are available), such as Braille, larger print or audio description.²⁵ They are thus dependent on other people, or require adapted formats, to gain access to their medicine information. However, ePI has the potential to radically change this; it could enable the use of screen readers and other software that makes information more accessible.

‘For me, and from the perspective of people with a visual impairment, the biggest benefit of ePI would be direct access – having the possibility to access the information myself.’

Christina Fasser, Retina International

ePI offers the possibility of streamlining access to up-to-date medical information in a person’s preferred language, overcoming potential language barriers. This was seen during the COVID-19 pandemic. The roll-out of COVID-19 vaccines and therapeutics in the European Union (EU) created an information overload regarding deployment, efficacy, symptoms and dosage requirements.²⁶ In this case, the use of a QR code with a direct link to the ePI in the appropriate language enabled timely access to the most recent, accurate information regarding COVID-19 vaccines for all people in Europe, regardless of their first language.²⁷ This centralisation can also help mitigate the risk of confusion or misinformation when too many sources of information exist.¹⁷

Improved adherence to medication, leading to better outcomes

As has been seen with electronic prescribing, ePI could potentially improve adherence to medication. It is estimated that, globally, almost 50% of people do not adhere to their physician’s prescription.^{28,29} Most people report forgetfulness, busy lifestyles and changing schedules when missing dosages and discontinuing their treatment.^{28,29} Data from the US suggest that non-adherence to prescribed medication is responsible for treatment inefficacy, increased hospitalisations and increased mortality.³⁰ It also results in a considerable cost to health systems.³¹ While data on the impact of ePI on adherence are not yet available, e-prescriptions or online prescriptions have been shown to have a positive impact, with e-prescriptions being associated with improved adherence compared with paper prescriptions.³² A survey also found that approximately 81% of people aged over 50 who were taking at least one prescription medicine preferred to receive e-prescriptions rather than paper versions to manage multiple prescriptions.³³

3. What are the potential benefits of ePI?

Other digital transformations have yielded promising results in improving outcomes, fuelling the promise of ePI. A systematic review and meta-analysis of the impact of electronic health records (EHRs) on healthcare quality found that organisations which properly implemented EHRs had 34% higher probability of adherence to clinical guidelines, while reducing medication errors by 54% and adverse effects linked to medicines by 34%.³⁴ The analysis also found significant associations between EHR use and reduced documentation time for healthcare professionals.³⁴

More portable access to medicine information

The provision of information digitally may be particularly important for people who have difficulty accessing healthcare facilities. The COVID-19 pandemic has demonstrated the value of telemedicine in improving access and support for people living in rural or remote areas, or for those who have difficulty travelling to appointments due to mobility impairments, transport exclusion and diverse working schedules.³⁵ Similarly, ePI could be made available instantaneously to people receiving medicines, regardless of their geographical location, without having to travel to a pharmacy or doctor.



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The portability of ePI is particularly useful for people accessing medication in another country. This is critical, as medicines may be available in different countries under different brand names, which can cause confusion and potentially lead to medication errors. This is exemplified in the case of people travelling or those displaced by war or conflict (*Case study 1*). To ensure people can always make fully informed choices about their medicines, it is particularly important to have instant and easy access to information during emergencies and in any rapidly evolving situation.³⁶

3. What are the potential benefits of ePI?



Case study 1. Fast deployment of ePI solutions for Ukrainian refugees

As a result of the war in Ukraine, the European Federation of Pharmaceutical Industries and Associations (EFPIA) and its member life science companies launched a technical solution to accessing product information, with the support of technology provider GS1.³⁷ Using a free, dedicated app, clinicians and patients could scan the data matrix code on medicine packaging and access the ePI leaflet in Ukrainian.³⁷ This meant the Ukrainian people who were displaced in Poland and other European countries had rapid, direct and free-of-charge access to essential product information on their prescribed medication, all available in their first language and via their mobile phone.

Environmental sustainability

ePI is an environmentally sustainable solution that will help reduce the carbon footprint of medicine supply chains once it entirely replaces paper product information. Current paper supply chains have a significant carbon footprint at each stage of production, from extraction of raw materials, to paper production, transportation and disposal or recycling.³⁸ Globally, more than 100 billion leaflets with product information on medicines are produced every year, generating



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an estimated 500,000 tonnes of carbon dioxide.² A recent US analysis showed that paper production for prescribing leaflets amounted to almost 11 billion gallons annually.¹² A transition to ePI would drastically remove many supply chain steps, making the system more efficient while considerably reducing its carbon footprint. Considering that electronic data storages also have a 'digital carbon footprint',³⁹ deploying ePI alongside paper will not necessarily decrease carbon footprints immediately; however, this is expected to be achieved once supply chains fully transition to digital-first solutions. Transitioning to ePI can be an important step in countries' efforts to achieve low-carbon, sustainable and climate-resilient health systems – a commitment made by over 70 countries as part of the Alliance for Transformative Action on Climate and Health (ATACH) spearheaded by the World Health Organization.⁴⁰

ePI could also significantly improve the efficiency of the supply chain, translating into clear benefits for patients. Currently, every time there is an update on a particular medicine, the product information needs to be updated with new information and reprinted in different languages, making the whole process highly inefficient, time consuming and largely environmentally unsustainable. When there is a label change, entire medicine packs become obsolete as changes are implemented within a legally prescribed timeline.^{2,37} Digital formats

3. What are the potential benefits of ePI?

not only are more environmentally sustainable, but would also broaden people's access to safe, up-to-date information while improving the efficiency and management of supply chains at the same time.⁴¹ Similarly, the ability of ePI to be available in multiple languages can help mitigate against product shortages by enabling easier supply without the need for relabelling.⁴¹ For example, using ePI, Singapore was able to launch three medications to market 12 weeks earlier than it would have been possible if paper labels were required, enabling earlier medicine access to patients.⁴²

Integration of information on medicines into the broader digitalisation of healthcare

'ePI supports our vision that we need to equip, engage and empower people with health information from trusted sources, that is more relevant for their specific circumstances.'

Anne Moen, Gravitare Health

Once ePI has been integrated with other digital health technologies, benefits for patients will become more tangible. Current product information in paper format is not interoperable with electronic health systems, such as e-prescriptions and electronic health records.¹⁷ An ideal scenario would involve electronic platforms where people's medicine information is semantically annotated, computable and easily accessible through mobile applications.²² If ePI can be integrated with digital records, such as EHRs or international patient summaries, data on medication can be included in a person's overall health record, providing up-to-date information wherever they are at any time. Other digital health innovations are currently being developed to help people access their medicine information anywhere, at any time, both through standardisation of information on medicines (*Case study 2*) and through creating technical interoperability between different digital platforms, including ePI (*Case study 3*). Integrating 'enhanced' ePI with these technologies could bring about significant benefits to people who take medication.

3. What are the potential benefits of ePI?



Case study 2. UNICOM: creating global recognition of medicines information

The UNICOM project focuses on the development and implementation of the International Organization for Standardization (ISO) standards that will allow the recognition of medicine information in different countries. This means that someone could go to any pharmacy, regardless of which country they are in, and see which local medicines are appropriate for them and which are different from their normal medication.²² This would improve the safety of e-prescribing and dispensing medicines across borders.^{36,43}

3. What are the potential benefits of ePI?



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Case study 3. Gravitare Health: improving people's relationship with their medication

Gravitare Health is a public-private partnership with members from Europe and the US.⁴⁴ It believes that engaging individuals in their own health can only be achieved with access to actionable, understandable, relevant and reliable information that meets their specific needs and literacy levels. Gravitare Health aims to: improve access to and understanding of health information; drive adherence; and improve outcomes by providing individuals with approved ePI content in an accessible way and with up-to-date information that better meets their distinct needs.

3. What are the potential benefits of ePI?

Integrated digital technologies can be important enablers in meeting people's health needs.

As far as pharmacovigilance is concerned – which encompasses the detection, assessment and prevention of adverse medication effects⁴⁵ – this could be especially beneficial to people taking multiple medications. Integration of digital technologies could facilitate the monitoring of medicine interactions and safety information for individuals, such as through EHRs, ePI and patient summaries that are semantically annotated and available in an integrated form in an accessible application. This would allow people taking multiple medications to easily access tailored safety information, which could foster better understanding of the side effects that are relevant to them personally.²²

‘The exciting vision of ePI is when we can migrate paper content towards computable understandability and present this in a tailored, accessible way through innovative apps.’

Dipak Kalra, European Institute for Innovation through Health Data

4. How to achieve an equitable and inclusive transition to ePI

‘If you take paper away and you don’t offer a better, more accessible digital solution, there will be a community that is disenfranchised and they will be the most vulnerable. We must not go digitally downhill before we go uphill.’

Dipak Kalra, European Institute for Innovation through Health Data

Developing equitable and accessible digital platforms

Like all health information, ePI must adhere to international accessibility standards. ePI should contain information that is authentic and unbiased, displayed in an appropriate font size and simple language.⁴⁶ The information should always account for the risk of low health literacy in users. Technical guidelines, such as the Web Content Accessibility Guidelines, can be used as blueprints to ensure that digital content is accessible for people with a broad range of abilities, including any sensory, learning or physical disabilities.⁴⁷

The development of ePI should build on existing frameworks for digital health equity. Guiding principles can be drawn from frameworks, such as Universal Design, that create an inclusive society which acknowledges human diversity, ensures equality and social inclusion on equal terms, and promotes respect for the abilities of every person (*Case study 4*).⁴⁸



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Case study 4. Application of health equity frameworks in the development of ePI

The US National Institute on Minority Health and Health Disparities Research Framework⁴⁹ was developed to outline clear spheres of influence that should be addressed to ensure an equitable transition to digital platforms or technologies. These should be taken into consideration when considering a transition to ePI,⁴⁹ and include:

- **digital literacy/digital self-efficacy**
- **attitudes towards use of digital solutions**
- **community infrastructure and healthcare infrastructure**
- **equitable design standards and appropriate technology policies and data protection standards.**

Co-creation of ePI with relevant patient communities

Engaging target users in the development of ePI will be key to ensuring it is inclusive and appropriate to everyone's needs. ePI offers an opportunity to avoid documented shortcomings of traditional paper formats of product information in terms of accessibility and usefulness of information provided.^{46 50-52} To create information that is culturally and age sensitive, and that meets the needs of a variety of people, patient groups should be involved from early stages of development.^{53 54} Input should be sought from a wide variety of stakeholders (demographic, patient, professional or otherwise), so that different perspectives and needs can be considered.^{55 56} The impact on patients of digitalising information, and any concerns about this, should also be addressed to guide further improvements.⁵⁵

'Patients should be involved from very early stages of any new digital solution. When developing text for ePI, this should be checked by patients for linguistic accessibility and for visual and auxiliary aids accessibility.'

Christina Fasser, Retina International

Efforts should also be made to involve people with different disabilities in the design of ePI.

People with disabilities are one group at particular risk of experiencing the digital divide.^{57 58} One study that assessed the accessibility, readability and operability of popular health websites found that 91% had detectable accessibility failures.⁵⁹ At the same time, this is also a demographic that can benefit significantly from ePI. To avoid these failings, ePI developers should make sure they integrate accessibility options or alternative features into ePI, so that people with visual, auditory or other disabilities can fully benefit from it. For example, innovative applications that provide auditory descriptions of the world to people with visual impairments are revolutionising the ability of people who are blind to 'see' written information.⁶⁰ Additionally, apps now exist that can recognise QR codes from a greater distance and use accessibility features such as audio assistance, larger fonts and contrast settings, making them more usable for people with diverse abilities.⁶¹ Interoperability between ePI platforms and the specialist software used by people with visual or other disabilities, such as screen readers, is also essential to make sure ePI can easily be adapted to their needs.

Recognising the risk of digital exclusion

Universal connectivity must be taken into consideration when planning for accessible implementation of ePI, particularly in lower-income settings. People's ability to engage with electronic platforms will also be influenced by other factors, such as geographical location,⁶² affordability,⁶³ and mobile phone access and use.⁶⁴ Community initiatives, such as increasing connectivity access in public spaces, including public libraries and pharmacies, may be helpful for people who do not have internet access at home.⁶⁵ It will be important to bring software, hardware, cloud computing, internet access and education together in one place.⁶⁶ Doing this in a coordinated manner, with engagement from community members who may not be digitally agile, will maximise the benefits of ePI for all individuals. Notably, these issues will be less of a concern when transitioning to ePI for hospital-based products, where patients rarely have access to product information and where safety information for medicines is often shared verbally by a healthcare professional.

'Engaging people with disabilities at the design stage of digital solutions is so important – too often, this is an afterthought, and innovations remain inaccessible as they are incompatible with the software people need to access digital information.'

Made Wikandana, Equity Initiative

5. An eye to the future: guiding principles for a successful transition to ePI

‘Governments can be the stakeholders that catalyse transformation. Having a coherent national digital strategy is crucial, so we can bring all relevant stakeholders together and move towards digital-first solutions.’

Dr Emanuele Capobianco, WHO Foundation

Preparing for an equitable and successful transition to ePI requires a systems approach and digital-first, forward-looking policies. Governments must engage with all relevant stakeholders, including life science companies, regulators, patient organisations and health technology developers, to advance equitable, digital-first solutions. Policy leadership is needed to ensure health systems are ready for a migration to digital solutions such as ePI. This will require appropriately adapted regulatory and legislative frameworks to ensure the highest standards of data protection are always upheld. Key components of this system readiness are described in *Figure 2*.



Governments must engage with all relevant stakeholders, including life science companies, regulators, patient organisations and health technology developers, to advance equitable, digital-first solutions.

Figure 2. Ensuring system readiness for a transition to ePI: key components



Provide appropriate information about ePI to all relevant stakeholders



Build ePI equitably, leaving no one behind



Accompany policy shifts towards ePI with strong local engagement with relevant communities



Provide appropriate training and support for healthcare professionals in the transition to ePI



Ensure multi-stakeholder collaboration to integrate ePI into broader digitalisation efforts

Provide appropriate information about ePI to all relevant stakeholders

Educating the public and healthcare professionals on what ePI is and how to use it is a critical starting point. This will be essential to help ensure people trust and engage with the information on an electronic platform.^{67,68} Building comprehensive knowledge bases around ePI and parallel digital technologies – such as electronic patient summaries and health monitoring applications – will also be essential to optimise their use and integration.

Build ePI equitably, leaving no one behind

At the most fundamental level, governments should ensure all individuals can access digital health information and have safe and affordable access to the internet. This includes meaningful use of digitally enabled health services, in line with universal health coverage and UN Sustainable Development Goals.^{69 70} These principles should extend to information about medicines.

It is also vital that any transition to ePI adheres to the highest principles of equity and inclusion. As an evolving digital solution, ePI presents the opportunity to leverage technical innovations and embed alternative features that can make it accessible and usable by all, including people with different disabilities who have typically been at risk of digital exclusion. Guiding principles such as Universal Design should be embedded into ePI development to ensure that each step of implementation is steered towards optimal effectiveness and equity.⁴⁸

Accompany policy shifts towards ePI with strong local engagement with relevant communities

Policy shifts towards ePI should come hand-in-hand with community engagement at the local level. This will help ensure that ePI is brought closer to the communities who may be at risk of digital exclusion. Principles can be taken from initiatives such as Information and Communications Technology for Development (ICT 4D) that aim to make digital solutions more equitable.^{65 66}

Involve patient communities and people at risk of digital exclusion in the design of ePI

Co-creation of ePI with patient communities will be essential to make sure information meets their needs. Engaging people at risk of digital exclusion, particularly people with disabilities, in the design of ePI will ensure that relevant accessibility features are built into ePI from the onset, making it accessible and usable by all.

Provide appropriate training and support for healthcare professionals in the transition to ePI

Involving healthcare professionals in the implementation of ePI is also needed to secure their buy-in and to support them in their communication with patients around ePI. Pharmacists play a critical role in guiding people to make informed decisions around eHealth and digital health,⁷¹ and strong engagement with this community will be important. Engaging primary and secondary care physicians will also be essential, to ensure they are well versed in what ePI is and can support their patients to use ePI to better understand their medication.

Ensure multi-stakeholder collaboration to integrate ePI into broader digitalisation efforts

The full potential of ePI will manifest itself once it is fully integrated into other digital health advances. To enable this potential, developers of ePI – pharmaceutical and digital health technology industries – should invest in upskilling themselves in medical knowledge, terminologies and semantically annotated ePI, and exploit synergies with other digital advances and technologies that can help expand the scope, reach and accessibility of ePI.

Like any digital innovation, fully integrating ePI into the future of healthcare will require a multi-stakeholder approach. Close collaboration between developers, regulatory authorities and the healthcare community will ensure the transition to ePI is fully embedded into the architecture of health and information systems, securing more accessible, equitable and safe access to information about medicines for all.

6. Looking ahead to a digital-first future for information on medicines

The promise of ePI comes with great expectations. Enhanced, computable and tailored forms of ePI have the potential to overcome many of the historical limitations to paper-based information on medicines for patients, making it more usable, accessible and tailored to each person's needs. ePI has the potential to improve access to medicine information, improving patient safety and medication adherence, and empowering people to better understand their medication and thus take more ownership over their treatment and care. Additionally, ePI promises to help streamline the flow of information within health systems, render supply chains for medicines more efficient and streamlined, and significantly reduce the carbon footprint of medicines, making their development more environmentally sustainable.

ePI will yield the most significant benefits when its enhanced forms are fully integrated alongside other digital platforms, allowing information to be tailored to the needs of each person. Securing this transition will require engagement from all relevant stakeholders as well as system-wide readiness for change. Crucially, engaging patient communities and people at risk of digital exclusion in the design and ongoing development of ePI will be essential to realise its full potential, optimise its accessibility and usability, and secure its full integration into future, digital-first health systems.

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