Towards electronic product information that meets the needs of everyone: Implications for patients, clinicians, and medical writers

Behtash Bahador,[1] **Trishna Bharadia,**[2] **Derek Stewart,**[3] **Christopher C. Winchester**[4,5]

[1] Center for Information and Study on Clinical Research Participation (CISCRP), Boston, MA, USA
[2] The Spark Global, Buckinghamshire, UK; Patient Author; Visiting Lecturer, Centre for Pharmaceutical Medicine Research, King's College London, London, UK
[3] Patient Advocate; Patient Author, Nottingham, UK
[4] Oxford PharmaGenesis Ltd, Oxford, UK
[5] Green Templeton College, University of Oxford, Oxford, UK

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Correspondence to
Christopher C. Winchester
chris.winchester@pharmagenesis.com

Abstract

In an age of increasing digitisation, pharmaceutical product information is evolving. This transformation reflects growing recognition among regulators of the value of patient engagement and widespread societal calls for increased transparency of and access to medical information. We consider the future of pharmaceutical product information, reimagining the electronic product information (ePI) as an interoperable and informative platform that links core product information to a range of supporting medical information resources. We consider the benefits that this evolution can afford different stakeholder groups in terms of increased transparency, enriched information provision, and tailored information solutions, as well as the potential challenges that will need to be addressed. We also discuss the critical role that medical writers can play in informing and shaping the future of ePI for the benefit of all.

ePI: What it is, where it began, and how it is beginning to evolve

"Product information" is the information about the efficacy, safety, and appropriate use of a drug that is approved by medicines regulators for distribution to healthcare professionals, patients, and the public. The term encompasses the product label, the packaging leaflet, and a more in-depth technical document that summarises the data underpinning the product approval and its approved use.[1] The packaging leaflet is the patient-facing information included within the medicine box that provides instructions for use and information about possible side effects. The more technical document is referred to as the "prescribing information" in the USA and as the "summary of product characteristics" in Europe. Product information has huge potential to support patient care and inform clinical decision-making, particularly if it evolves in response to user needs to embody principles of trust and transparency.[2]

Product information is already evolving. It was originally a paper-based document designed by regulators primarily for expert audiences, but regulators are already recognising the potential value in making the information more user-friendly so that it can meet the needs of a range of different stakeholders, including patients.[3] These changing attitudes to product information have been accompanied by several complementary drivers and enablers of change, including environmental initiatives to reduce packaging,[4] the progressive shift towards digitisation of information, increased emphasis on patient–physician shared decision-making practices, and calls for increased transparency in healthcare information (Figure 1). Together, these social and regulatory factors have converged to create a unique opportunity to reimagine product information as an accessible and transparent electronic resource tailored to a range of stakeholder needs.

As part of an ongoing movement towards digital transformation, the package leaflet is already available in some regions in an online PDF format, as a complement to the traditional paper-based form.[5] The content of the PDF mirrors the paper-based product information,[4] but it has the advantage of being searchable and shareable, and it can also be easily enlarged to aid legibility. The next step is to transition towards true electronic product information (ePI) – an interoperable and informative platform linking core product information to a range of supporting medical information resources, including links to additional patient information resources.

> Traditionally, discussions about product information evolving from paper-based to digital formats have been approached from an environmental and sustainability perspective.

Traditionally, discussions about product information evolving from paper-based to digital formats have been approached from an environmental and sustainability perspective.[6] These considerations should be expanded to reflect the potential that ePI offers for improved transparency of medical information, the associated health equity benefits, and the potential for companies to roll out new medicines more quickly with real-time updates to safety information to reflect post-authorisation studies, should a paper leaflet not be

required. Realising ePI as a layered content platform would allow all stakeholders (including healthcare professionals, patients, carers, and policymakers), to access information relevant to and appropriate for their own specific needs; in the case of patients, potentially supporting them with medication compliance and to engage in more informed, shared decision-making.

Recent revisions to traditional regulatory positions on product information reflect growing recognition of the importance of engaging patients as partners in healthcare decision-making.[7] The official US Food and Drug Administration (FDA) position (1938) stated that product information should be for expert audiences and not necessarily understandable by the lay person.[8] A FDA consultation published in 2023 highlighted evolving regulatory attitudes to product information, driven by increased recognition that providing transparent, patient-friendly, written information about prescription drugs can improve health outcomes.[3] In addition, in 2020, the European Medicines Agency (EMA) published key principles to guide the development and use of ePI, with a focus on improving accessibility, searchability, and multilingual capabilities.[9] The EMA's adoption of the HL7 Fast Healthcare Interoperability Resources standard and participation in a one-year ePI pilot project in Denmark, the Netherlands, Spain, and Sweden between July 2023 to August 2024 have further advanced digital interoperability within healthcare systems.[10] In addition, technical requirements for structuring product information from Japan and the USA have laid the foundations for ePI in these regions.[11,12] The increasing digitisation, standardisation, and interoperability of medical information creates an environment ripe for collaborative approaches to reimagining ePI for the benefit of all.

Photo: Freepik

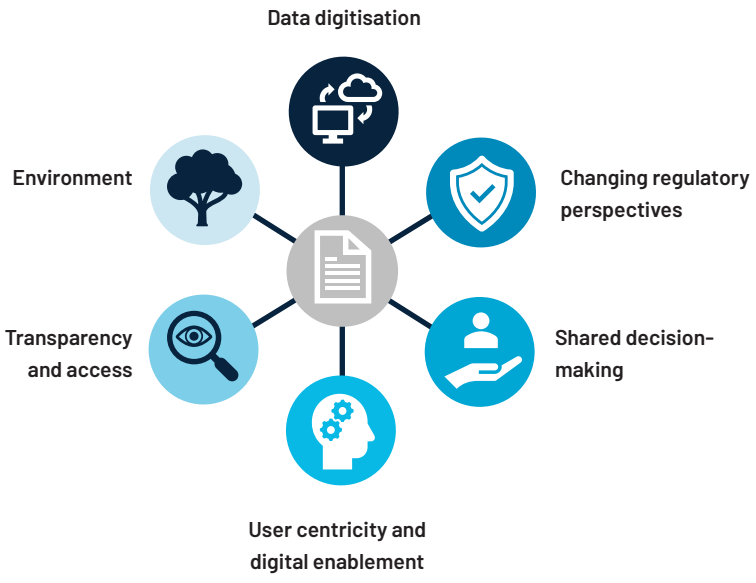

Figure 1. Key factors driving the evolution of product information

ePI can optimise access to product information that meets the needs of all stakeholders

By harnessing the opportunities presented by digitisation of information, ePI platforms could provide an opportunity to tailor information for all stakeholders, ensuring everyone has access to reliable, transparent, verified, compliant, and appropriate product information relevant to their needs.

There is already a wealth of high-quality medical information available online or in a digital format, and ePI offers an opportunity to link these materials together to increase discoverability and transparency. Including live links in ePI has the potential to increase access to the highest-quality, peer-reviewed evidence and aggregate key medical information at a single, centralised location. This could also increase the discoverability of assets that might otherwise be overlooked in supplementary materials, such as plain language summaries of publications, infographics, and guidance for non-healthcare professionals on how to interpret clinical trial data. Indeed, ePI could become a tool to improve health literacy and to enhance accountability, transparency, and trust in medical research.

Table 1. Considerations, opportunities, and challenges/risks associated with ePI

Consideration	Opportunity to:
Cultures/languages	Adapt materials to align with different cultural practices and languages in order to maximise impact across a wide range of audiences
User attitudes and behaviours	Address different users' attitudes and behaviours to healthcare information in order to increase engagement
Health literacy	Develop and link to a broad range of materials suitable for differing levels of health literacy and information needs among users (e.g., plain language summaries for patients and non-specialist healthcare professionals; linked clinical trial information for healthcare professionals and researchers)
Usability	Consider features such as font size controls, and using a narrator to read text aloud in order to increase access for users with vision and/or reading challenges
Learning modes	Develop and clearly signpost materials appropriate for different learning styles (e.g., formats tailored to auditory, visual, and reading/writing learners)
Digital equity	Offer digital formats as an addition to paper-based ePI materials to support a transition from paper-to-digital formats, recognising differing levels of digital access and comfort across potential user groups
Empowering caregivers	Enable caregivers (local or remote) to provide informed support for relatives/friends by allowing them digital access to medicines information
Trust	Counteract medical misinformation by linking to high-quality, evidence-based materials (e.g., peer-reviewed and regulatory-approved information), ideally aggregated through effective use of metadata

Abbreviations: ePI, electronic product information

Examples of the ways in which ePI could potentially benefit different stakeholders include:

- Improving patient care by directly linking ePI to healthcare applications that support patients in self-management
- Offering patients and carers links to additional information about possible drug–drug interactions and contraindications for newly and currently prescribed medications with real-time updates to safety information, as required, to reflect emerging data from post-authorisation studies
- Allowing a carer who may be in a different city to the family member they are caring for to access information on appropriate dosing to help "guide their relative at a distance"
- Enabling patients to access a translation (or more easily understood version) of the product information for their newly prescribed medication that is specific to their indication
- Supporting visually impaired patients owing to the adaptability of font size and compatibility with software that reads text aloud
- Countering misinformation about prescribed medicines through enhanced transparency – linking users with reliable source information (e.g., ClinicalTrial.gov records, plain language summaries [including clinical trial lay summaries], and peer-reviewed journal publications of the study results).

By initiating conversations around digitally optimised ePI early in the development of a medicine, a wide range of linkable resources could be efficiently developed in anticipation of drug approval, including materials that supplement the required paper-based product information leaflet and address additional stakeholder needs. Thinking digitally from the outset allows materials to be prepared throughout the development and lifecycle of a drug with the potential for ePI curation in mind. The report from the aforementioned European ePI pilot included recommendations for supplementary guidance and business process updates to support integration of ePI alongside existing practices.[10]

In summary, a standardised ePI template to address the considerations outlined in Table 1 has the potential to reduce health inequity, improve understanding, increase transparency, promote global engagement for all stakeholders, and help to support informed shared decision-making. As with all innovations, however, an evolution to ePI would need to be handled with consideration to optimise the potential benefits while minimising possible unwanted implications, such as exacerbation of existing inequalities in digital and health literacy.

Barriers to realising the positive potential of ePI may need to be overcome

It is important to recognise that digital literacy and digital access vary between different demographic and sociodemographic subgroups, and between different regional and national locations. Until substantial improvements are made towards global digital equity, it is important for regulators, healthcare professionals, and medical writers to be mindful of ensuring that printed paper copies

of all components of product information remain available to those who might otherwise be at risk of digital exclusion.[6,13]

The potential drawbacks of digitising product information should also be considered from the perspective of healthcare professionals and pharmacists who may fear that ePI could increase the time and cost burden associated with providing accessible and up-to-date information to patients and caregivers. Furthermore, despite the focus on the environmental benefits of ePI, the digital storage requirements for ePI combined with the necessary retention of the paper format do not necessarily make ePI a carbon-free alternative to paper-based product information.[6]

Key considerations and opportunities for ePI, as well as associated challenges and risks, are detailed in Table 1.

Considerations for the future of ePI

ePI has the potential to address challenges associated with understanding product information, to offer patients, healthcare providers, and other stakeholders options and variety in the format and scope of the information available about a product. Ultimately, by linking to additional medical information sources, ePI could support patients to improve self-management and informed, shared decision-making. Currently, extensive work is ongoing to increase the availability of online patient information in multimedia formats, and the opportunity to integrate this with ePI should be explored in the future.[14]

The future success of a transition to ePI is part of a broader societal move towards digitisation. This will require medical writers and healthcare communications professionals to continue to build a solid foundation of high-quality, accessible, and discoverable medical information that is suitable for everyone. The continued evolution of the ePI landscape will also be contingent on the pharmaceutical industry, regulators, healthcare professionals, and medical writers working together to allocate resources to the development of ePI platforms and build multi-stakeholder partnerships to share best practices and communicate the value of ePI for all. This should be accompanied by raising awareness of the importance of providing appropriate, tailored information about ePI to all stakeholders.

Meanwhile, medical writers have a key role in developing the information infrastructure to help optimise ePI (see Figure 2) by:

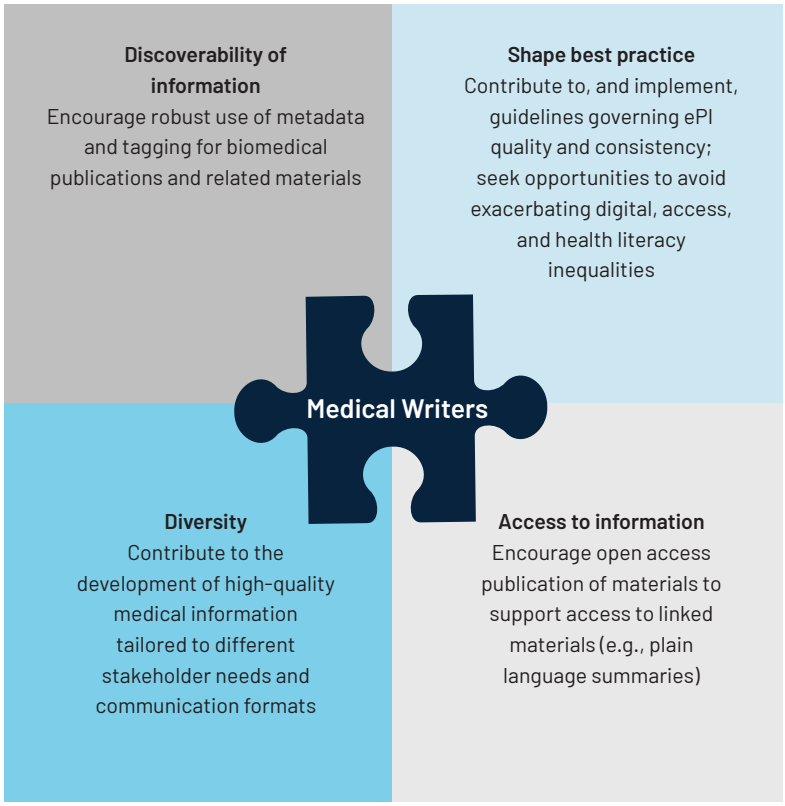

Figure 2. Medical writers have a key role to play in the evolution of ePI

Abbreviations: ePI, electronic product information.

- Publishing with open access to support transparency and trust
- Using metadata and tagging to support discoverability and content linkage
- Developing accessible summaries, such as plain language summaries, infographics, animations, and other multimedia-based resources to support the needs of stakeholders with different levels of health literacy and learning modes
- Conveying complex medical information in a more human-centred way
- Developing peer-reviewed articles cognisant of the fact that the data and interpretation they contain, and extenders they carry (e.g., accessible summaries, podcasts, videos), might one day (subject to future regulatory agreement) be linked through the ePI to aid user comprehension
- Creating guidelines for the development of ePI to support quality and consistency
- Ensuring that ePI ameliorates rather than exacerbates existing challenges and inequities in access to health information
- Leveraging existing tools, including considered use of artificial intelligence capabilities, to help adapt, translate, and aggregate medical content
- Proposing viable and streamlined processes for linking ePI to relevant sources

Medical writers have a key role to play in the flow of information from research studies to healthcare professionals, patients, and other stakeholders. They can therefore make valuable contributions to inform and shape the evolution of the ePI landscape and the medical materials that could help to realise the potential of ePI, and can raise awareness of the potential benefits of ePI for everyone.

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The authors declare no conflicts of interest.

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Author information

Behtash Bahador is the Director of Health Literacy at the non-profit organisation Center for Information and Study on Clinical Reserach Participation (CISCRP) and holds a Master of Science in Health Communication from the Tufts University School of Medicine. He has collaborated with a range of stakeholders to establish and implement patient- and public-centric initiatives across the drug lifecycle.

Trishna Bharadia is a visiting lecturer on patient engagement at King's College London's Centre for Pharmaceutical Medicine Research and has won multiple awards during her 15 years of working in patient advocacy and engagement with a range of stakeholders.

Derek Stewart is Honorary Professor at the University of Galway for his work as a patient advocate involved in health research. He was founding Chair of the National Cancer Research Institute's Consumer Liaison Group; former positions include Associate Directorship of the National Institute for Health Research – Clinical Research Network.

Christopher C. Winchester is Chief Executive Officer of Oxford PharmaGenesis Ltd and Associate Fellow of Green Templeton College, University of Oxford, Oxford, UK. He co-founded Open Pharma, is a former Chair of the International Society for Medical Publications Professionals, and has over 20 years of European and global communications experience.