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Short communication

Electronic product information (ePI): Expanded access to information on medicines in the European Union (EU)

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Introduction

Product information (PI) of the medicines is regulated, scientifically validated information that assists healthcare professionals (HCPs) in prescribing and dispensing the medicine and informs patients about its safe use. PI comprises the summary of product characteristics (SmPC, intended for HCPs), labelling (packaging information) and package leaflet (PL, intended for patients) (EMA, 2020 a). The development of ePI is intended to improve access to up-to-date PI on medicines when and where it is needed. The European Medicines Agency (EMA), in collaboration with Heads of Medicines Agencies (HMA) and the European Commission (EC), has developed key principles through stakeholder consultations to guide the development and use of ePI in the EU (EMA, 2020 b). The key principles outline: how ePI benefits public health, creates efficiency gains for regulatory systems, aligns with the existing legislative framework and complements the paper package leaflet, fits into the EU's multilingual environment, and interacts with other ongoing digital initiatives at EU and global level. (EMA, 2020 a).

Chronology

In March 2017, EC published a report, which concluded that despite ongoing efforts to make the PI easy-to-read and useful, there is a scope for improvement on how information on medicines is conveyed to patients and HCPs. Consequently, in November 2017, EMA published an action plan to improve the PI for every medicine authorized in the EU (EMA, 2017). One of the crucial areas of this plan is to explore how electronic or digital means can be used to improve accessibility to medicines information by patients and HCPs. It also includes other initiatives: making the PL easier to understand for EU citizens, updating the EU guidance available for companies to prepare the PL, and strengthening patients' input during the preparation of the PL.

Throughout 2018, EMA and the EC organized a multi-stakeholder workshop (bringing together patients, HCPs, the pharma industry, academia, etc.) to develop key principles for the use of electronic formats. The workshop's outcome was a draft proposal for 'key principles' overviewing needs, concerns and a common approach moving forward for everyone involved in ePI. These key principles were the subject of a 6-month public consultation (from January 2019, until July 2019) and now include concluded updates representing EMA-HMA-EC guidance on ePI and form the basis of follow-up implementation plans for ePI (EMA, 2020 b).

In January 2020, key principles for ePI for EU medicines were announced (EMA, 2020 a), followed by the publication of the draft Common EU Standard for ePI on GitHub at the end of May 2021. At the end of September 2021, the proof-of-concept prototype and the common EU standard for ePI were completed (EMA, 2021).

Key principles

ePI is an authorized, statutory PI for medicines in a semi-structured format created using the common EU electronic standard and adapted for electronic handling, which allows spreading via the world wide web, e-platforms, and print. The common EU electronic standard refers to the technical features (including markup language, controlled vocabulary, and interoperability specifications) agreed by EMA, HMA, National Competent Authorities (NCAs), EC, pharmaceutical industry representatives, and patients and HCPs. ePI will enable the dissemination of the

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newest, unbiased, regulator-approved PI for all medicines in the EU. ePI will support the provision of the latest information on a medicine's safety, benefits, conditions of use etc., so that the correct information is available to the right HCP/patient at the point of need. ePI will facilitate the creation of PI accessible to everyone, including users with diverse abilities. Accessible formats like large fonts or high screen contrast will provide complete and balanced product information to users in formats suitable for their needs. ePI on the web will be accessible to screen readers, web and mobile applications, convertible to large font and amenable to other accessible formats. ePI will enable increased efficiency in the management of PI during regulatory procedures. By enabling PI changes across all relevant PI annexes and products, ePI could eliminate many manually performed tasks and redundancies that are potential sources of error. ePI will provide information on medicines that is amenable to analysis and could be used to increase knowledge by facilitating the study of characteristics of current EU medicines. ePI does not supersede or negate the pharmaceutical legislation (Article 58 of the Directive 2001/83/EC) to include a PL in the packaging of all medicines or directly convey all information required (by Articles 59 and 62 of the Directive 2001/83/EC) on the outer or immediate packaging. Since the current legislation does not require an electronic version of PI, the use of ePI will not constitute a new legal obligation. ePI is intended to deliver of the complete regulator-approved medicine PI only. It ensures maximum data protection in accordance with Regulation 2016/679 (General Data Protection Regulation) and Regulation 2018/1725 applicable to EU institutions. ePI format will be used for the PI of all medicines authorized in the EU through EMA and NCAs from submission and throughout the evaluation process providing high-level governance. All stakeholders, including pharmaceutical companies and regulators, are expected to commit to implementing the common electronic standard for creating ePI for all EU medicines. However, timelines and processes for implementation will be flexible and amenable to the available resources and priorities at a national level. ePI shall support all official EU languages and Icelandic and Norwegian so that EU citizens can read ePI in their preferred language when authorized ePI in that language is available. ePI will interface and interact with many EU and global initiatives. Related services should work together, within and across organizations or domains.

Application Programming Interface (API)

An API is a set of defined routines, protocols, and tools for building software applications. It expresses a software component in terms of its operations, inputs, outputs, and underlying types. The ePI API is built on the Fast Healthcare Interoperability Resources (FHIR) specification (EMA, 2021). FHIR is an open international modus operandi for exchanging data between different computer systems, published by developing organization Health Level Seven (HL7). FHIR enables a searchable, web-based representation of healthcare information, which can be transferred across devices (Saripalle et al., 2019).

Conclusion

The ePI initiative was launched to support the digital transformation of healthcare across the EU and the commitment laid out by the EC to prioritize innovations that will empower citizens and build a healthier society. It is also in line with EMA's current digitalization efforts to make the best use of available resources and prepare for future challenges. Digital platforms open additional possibilities to disseminate the PI electronically and better meet patients' and healthcare professionals' needs for accessible, trustworthy and up-to-date information on medicines available at the right time.

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Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC (General Data Protection Regulation).

Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.

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