Public consultation on key principles for electronic product information for human medicines in the EU

Introduction

The purpose of this public consultation is to seek views from the public on EMA's proposed key principles on electronic product information (ePI) for human medicines authorised in the EU. These principles will be used to guide the progress of future work on ePI. The consultation will remain open until July 31, 2019.

This questionnaire should be completed once you have read the draft key principles document. Additional background information on the initiative is available in the ePI workshop report.

Data Protection

By participating in this survey, your submission will be assessed by EMA. EMA collects and stores your personal data for the purpose of this survey and, in the interest of transparency, your submission and identity will be made publicly available.
For more information about the processing of personal data by EMA, please read the privacy statement.

Your name

Rita Kessler on behalf of Prescrire team

Your email

rkessler@prescrire.org

You are a:
- ○ Member of the public
- ○ Patient/consumer
- ○ Patient/consumer organisation
- ○ Healthcare professional
- ○ Healthcare professional organisation
- ○ Academic
- ○ Media
- ○ Pharmaceutical industry
- ○ Health Technology Assessment Body
- ○ EU/EEA national competent authority
- ○ European Institution
- ○ EU agency
- ○ Non-EU regulatory authority

◉ Other

If other, please specify:

> Not-for-profit organisation – medical journal – made up mainly of health professionals, committed to providing independent information on drugs, therapeutic and diagnostic strategies

Name of your organisation:

> PRESCRIRE

Indicate the key principle you would like to comment on (select all that apply):
- ☑ 1.1 ePI
- ☑ 1.2 Common EU electronic standard
- ☑ 2.1 Expanding access to information
- ☑ 2.2 Accessibility
- ☑ 3.1 Complementing paper package leaflet
- ☑ 3.2 Open access to regulator-approved information
- ☐ 3.3 Data protection
- ☑ 4.1 Governance
- ☐ 4.2 Flexibility in implementation
- ☐ 5.1 Multilingual ePI
- ☑ 5.2 Interoperability

Detail your comment, rationale, the document line number and any proposed changes for principle 1.1 ePI:

> Statement
> Lines 87 and 88 state that ePI is adapted for electronic handling and allows dissemination via the world wide web, e-platforms and print. Currently PI is available via EU or national databases or in print form. Regulators should promote the dissemination of ePI through national competent authorities and/or on the European Commission and EMA websites. These websites should be user-friendly.
> In respect to the current legislation and to prevent any misuse (for promotional purposes for instance), it should be required that the dissemination by a third party of one or several components of ePI (SmPC, labelling and/or package leaflet) via the world wide web, e-platforms or in print form, should concern the full file(s) (comprehensiveness) while dissemination/publication of parts or extracts be prohibited.

Detail your comment, rationale, the document line number and any proposed changes for principle 1.2 Common EU electronic standard:

> Statement
> Lines 110-112 state that the common standard for ePI in the EU refers to the technical features agreed by regulators and stakeholders. It is unclear what is precisely understood by "regulators" and "stakeholders". Those entities participating in the process should be listed beforehand and competent member state authorities should be consulted for agreement on this process. Regulators and authorities should have the final word on the common standard to be put in place.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.1 Expanding access to information:

> Lines 143 – 144: EMA, HMA and the European Commission acknowledge that many future applications of ePI cannot currently be predicted. It should however be made sure that the outreach to electronic ePI will always be fully under the Regulators' control. EMA and other competent authorities should assess the proper use of the electronic handling and dissemination of ePI (conformity and comprehensiveness). EMA and other competent authorities have a duty to guarantee the quality of the dissemination of ePI and to avoid any deregulation.
>
> Lines 160 – 164: as outlined, ePI will enable wider availability on a range of platforms. To guarantee the public health imperative, the source of information and of publication plays a key role. In respect of current EU legislation, ePI should be hosted on national competent authorities and/or on the European Commission and EMA websites. Competent Member state authorities should decide if and on which other officially controlled plateforms ePI might be made available.

Detail your comment, rationale, the document line number and any proposed changes for principle 2.2 Accessibility:

> Statement
> Lines 185-188: facilitated access to ePI, especially in adapted formats for consumer/patients with specific needs is welcome. Enhancing the ePI readability and patient input in the development and testing by lay persons should be considered as well as a priority.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.1 Complementing paper package leaflet:

> We welcome and fully support the statement that the generation of ePI does not remove or replace the currently available paper format included in the medicines package. We also welcome the suggestion that the paper PL should include a statement directing to the ePI as the most up-to-date version of the PL (line 217). This should be done by including a QR code and/or the link to the ePI. All leaflets (paper and electronic versions), should clearly mention its date of validation.

Detail your comment, rationale, the document line number and any proposed changes for principle 3.2 Open access to regulator-approved information:

> Line 223 states that "ePI should always be published as open data, freely accessible for use and reuse". As we mentioned under heading 1.1 on ePI, the reuse and the dissemination of one or several components of ePI - the SmPC, labelling and/or package leaflet – might be possible provided the file is published in full while the dissemination of selected extracts or parts should be prohibited.

Detail your comment, rationale, the document line number and any proposed changes for principle 4.1 Governance:

> Lines 263 – 264: we fully support the dissemination of ePI through regulator and public websites at EMA and Member State levels.
> Lines 284- 287: we also support the suggestion to put in place a pan-European medicines web portal providing a central point for access of ePI for all centrally and nationally authorised medicines. It is important to make it user-friendly and to promote its use among the public.

Lines 263-264: we see the utility to use ePI for electronic health records and e-prescribing systems. However, this use should take place under the control of competent authorities.

Lines 267 – 268: it is stated that ePI will be made available for use by third parties who can reproduce them and make them available to patients and healthcare professionnals. As mentioned previously, third parties intending to disseminate ePI should be required to reproduce them in their integrality while disseminating parts or extracts should be forebidden. To be considered as official approved document/file, ePIs have to be considered in their integrality. As ePI are anyway disseminated through public websites, third parties who would like to use them for dissemination should include the direct link to the public website(s).

Detail your comment, rationale, the document line number and any proposed changes for principle 5.2 Interoperability:

Lines 371 and 372 mention that ePI will be interoperable by design with eHealth initiatives and EU Telematics projects, and will consider national infrastructures and global health standards. We consider that national competent authorities have to be consulted on interoperability aspects. This should not be dealt alone by EU initiatives and projects.

Enter any general comments you may have:

Access to reliable and updated official approved product information is essential for healthcare professionals and patients. In order to protect public health, Prescrire invites EMA, the HMA and the European Commission also to strive for improvement of the product information and to make sure, as highlighted several times in the consultation paper, that any initiative resulting from the current consultation process is fully in line with the current legislation and respects the EU agreement to uphold the ban on DTCA in Europe. The provision of public access to officially approved product information falls under the role of competent authorities, notably by their publication on national competent authorities and/or on the European Commission and EMA websites. As outlined in the consultation paper, access to the ePI should always be considered as an additional option to the printed version of the patient leaflet provided within the product package.

Thank you very much for your contribution. We value your opinion and encourage you to inform others who may be interested about this consultation.

Contact

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