Submission of comments on 'Reflection paper on linking to electronic product information (ePI) from EU medicine packages'

Fields marked with * are mandatory.

Submission of comments on 'Reflection paper on linking to electronic product information (ePI) from EU medicine packages'

The public consultation runs from 31 March 2025 to 30 June 2025.

Contributors to the public consultation are asked to submit comments via this survey. Comments not provided via the survey may not be processed.

Before submission, a draft of the comments can be saved. Once submitted, comments can be edited (by 30 June 2025) by clicking on "Edit contribution" at the link https://ec.europa.eu/eusurvey/ and entering your ID contribution that can be found on the pdf copy of your submission sent via email.

When you have completed the survey, please use the Submit button at the end to submit the comments to the European Medicines Agency.

Data protection statement and consent

You are invited to provide your organisation or name, country and email address for the purpose of this public consultation.

Publication of data
The following data collected in this survey will be published on the EMA website at the time of issuing the final paper subject to this survey:

- organisation name (the entity on behalf you respond to this survey)
- or your name (only if you do not respond to the survey on behalf of an organisation)
- your view/comments on the topics concerned

Country information and your email address will not be published.

Please be aware that the sender of the survey response is responsible to not disclose any personal data of third parties in the response.

Processing of data

All personal data provided within this survey will be processed in accordance with Regulation (EU) 2018 /1725 on the protection of individuals regarding the processing of personal data by the Union Institutions and bodies on the free movement of such data.

For more details on how EMA processes personal data, please refer to the EMA Data Protection Notice for surveys conducted via EUSurvey.

If you have any complaints or concerns about the processing of your personal data, you can contact EMA's Data Protection Officer at dataprotection@ema.europa.eu.

You can contact the Internal Controller at s-datacontroller@ema.europa.eu

You may also lodge a complaint with the European Data Protection Supervisor: edps@edps.europa.eu.

☑ Please check to confirm that you have read and understood the Data Protection Statement and that you consent to the processing of your personal data.

☑ Please check to confirm that you consent to possibly be contacted by EMA in relation to your survey responses to support the finalisation of the document subject this survey.

☑ Please check to confirm that you consent to the publication of your organisation name, your name (only if you do not respond to the survey on behalf of an organisation) and your survey responses on the EMA website at the time of issuing the final paper subject to this survey.

Your details

* Name of organisation or individual

Standing Committee of European Doctors (CPME)

* Country of organisation or individual

Belgium

* Email

diogo.teixeira.pereira@cpme.eu

General comments

General comments

Enter general comments (i.e. comments not pertaining to any particular line of text in the paper) in the table below.

	General comment
1	While digitalization offers opportunities to enhance information delivered to patients or healthcare professionals, we strongly believe that the electronic product information should never replace the paper version included in medicine packets, but remain complementary. In this sense, the electronic product information should never replace the paper form. More specific remarks that we have to the eLeaflet: • Any form of advertisement linked to the electronic versions must be strictly prohibited. No push notifications should be installed in user's phone. • No personal data should be collected or stored for the simple fact of consulting the electronic leaflet. Depending on how it is set up, the system could collect the Internet Protocol (IP) address of the user patient or healthcare professional or healthcare facility, use cookies or other surveillance tools to single out individuals, identifying their behavior or habits, making a profile of users. • The QR code or links can send the patient to a wrong website, or to a general part of the pharmaceutical company website, rendering difficult to understand which leaflet is the correct one for my case. • Electronic instructions for use imply a mobile phone or a computer; electricity or charged battery; access to the internet. If you are in the countryside with poor or no internet connection, you will not be able to access the leaflet. It implies digital health literacy. Recently, CPME together with patients, nurses, community and hospital pharmacists, hospitals and healthcare services, consumers, older people, health insurance funds and not-for-profit health mutuals released a joint statement stressing the need to maintain paper package leaflets, and use electronic leaflets as a complementary tool (see it here: https://www.cpme.eu/api/documents/adopted/2025/03/cpme.2024-143.joint.statement.epi.17032025.pdf). There was also a presentation on this at the last EMA Healthcare Professionals and Patients /Consumers working parties joint meeting (https://www.ema.europa.eu/en/documents/presentation/presentation-joint-statement-epi-d-teixeira-pereira_en.pdf).
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Executive summary

1. Executive summary

Enter comments indicating the line number(s) to which the comment pertains, the comment and rationale, and proposed text (optional).

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Introduction

2. Introduction

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2D code

3.1 2D code

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Solution to scan and link to ePI

3.2 Solution to scan and link to ePI

Enter comments indicating the line number(s) to which the comment pertains, the comment and rationale, and proposed text (optional).

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Displayed content

3.3 Displayed content

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ePI annotated with data carrier identifiers

3.4 ePI annotated with data carrier identifiers

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3.5 Governance

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Established, existing solutions

4.1 Established, existing solutions

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Over-the-counter medicines

4.2 Over-the-counter medicines

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4.3 Parallel trade medicines

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Primary and secondary packaging

4.4 Primary and secondary packaging

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Change of excipients

4.5 Change of excipients

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Human readable URL

4.6 Human readable URL

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Printed package leaflets

4.7 Printed package leaflets

Enter comments indicating the line number(s) to which the comment pertains, the comment and rationale, and proposed text (optional).

	Line number(s)	Comment and rationale	Proposed text
1	63	Any form of advertisement linked to the electronic versions must be strictly prohibited. No push notifications should be installed in user's phone. Consequently, the inclusion of promotional elements in information provided via mobile device technologies is strictly prohibited. Recommended to change "can not" to "strictly forbidden".	Information provided through mobile device technologies is strictly forbidden from containing promotional elements.
2	171-172	Recommended to replace "should" by "shall" to indicate a mandatory requirement for ensuring information security andavailability.	Provision of content should take into account factors such as security and availability. Measures shall be in place to ensure that the information provided cannot be compromised and that there is no interruption in service.
3	275-278	Paper package leaflets must be maintained, and electronic leaflets should be used as a complementary tool in order to leave no one behind. Package leaflet is a vital component of the information provided to patients on the safe and effective use of the medicines they take, which is a consideration under the benefit/risk analysis Package leaflets are important for people who may not have access to smartphones or the internet, or choose not to use them (due to age, geographical location, disability, health, income, religion or social situation). At present, providing the paper leaflet in the medicine packages is a key regulatory responsibility of pharmaceutical companies, who also bear the costs. If the paper leaflets are removed from the packages, the	The paper package leaflet is particularly important for consumers with low digital literacy or limited access to smartphones or the internet, or choose not to use them (due to age, geographical location, disability, health, income, religion or social situation). The components mentioned above (3. Components of a solution for ePI access) can facilitate scan and print services that can guarantee that the patient can have access to a paper package leaflet, if this is the preferred format. Providing the paper leaflet in the medicine packages is a key regulatory responsibility of marketing

		burden, practicalities and costs (time, paper, printer, ink, internet connection, etc) of printing an ePI would fall on the pharmacist or on the patient.	authorisation holders and it needs to be kept in order to avoid further costs to patients or other healthcare professionals.
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Veterinary medicines

4.8 Veterinary medicines

Enter comments indicating the line number(s) to which the comment pertains, the comment and rationale, and proposed text (optional).

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Real-world examples

5. Real-world examples

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Japan

5.1 Japan

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Spain

5.2 Spain

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5.3 Germany

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Nordic countries

5.4 Nordic countries

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5.5 Ukraine initiative in Poland

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Conclusion

6. Conclusion

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Thank you for your contribution.

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