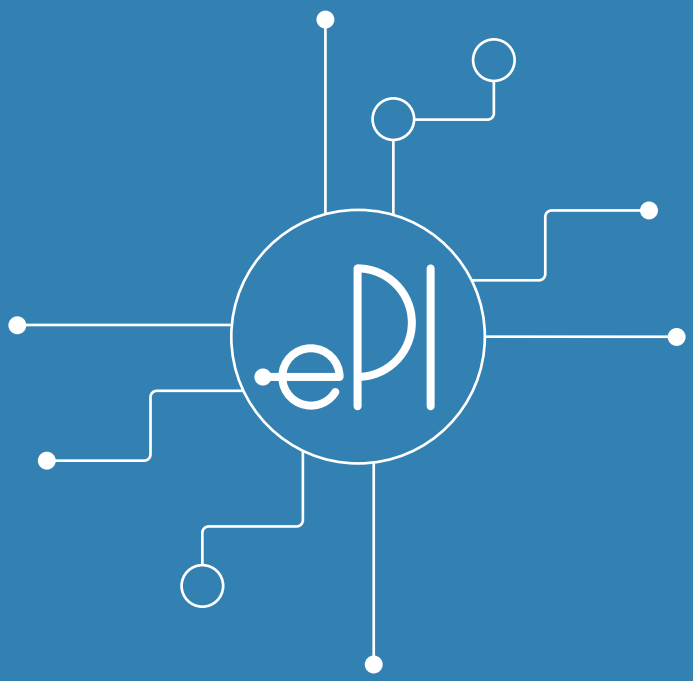
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

European Commission

Report on public consultation

'Electronic product information for human medicines in the EU: key principles'



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1. Background of consultation

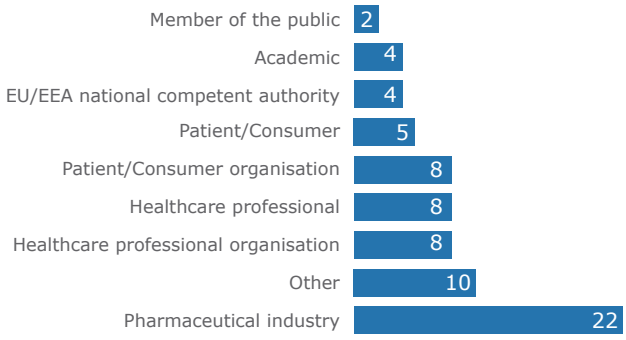
A report from the European Commission (EC) in March 2017, and a subsequent EMA action plan, identified areas where medicines' product information (PI), which includes the summary of product characteristics (SmPC) and package leaflet (PL), could be improved to better meet the needs of patients and healthcare professionals (HCPs) and proposed actions to address these shortcomings. Throughout 2018 and 2019, a joint EMA-HMA-EC collaboration has worked on one of these actions: the development of an electronic format (ePI). This action has been prioritised as it will ensure patients have timely access to up-to-date information and coordination among the many initiatives ongoing in the EU. The current scope of this work is all human medicines authorised in the EU.

A workshop held at EMA on 28 November 2018 brought stakeholders together to discuss their needs and concerns and decide how to move forward with a common approach. The outcome of the workshop was a draft proposal for 'key principles', which will form the basis of follow-up implementation plans for ePI. The key principles were released for public consultation (January to July 2019).

The comments received during the consultation were reviewed by the Support for Better Use of Medicines HMA Working Group and the 'key principles' have been updated accordingly. The finalised 'key principles' are published on the EMA website and communicated to stakeholders through meetings and dissemination channels.

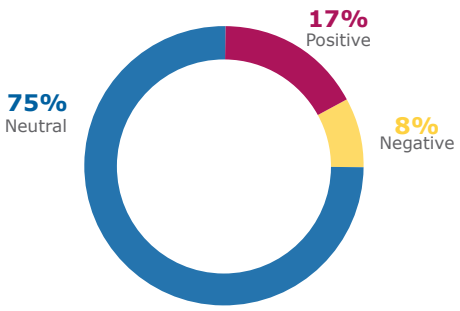
2. Contributions

In total, 71 contributions were received. The affiliation of the contributors is shown in the graph below. Contributors in the category 'Other' included consultants, a medical journal, companies and associations [software, medical gas producers, printing, data] and a social insurance association.



Most contributions received consisted of multiple comments on different aspects of the 'key principles'. Dividing contributions into individual comments resulted in a total of over 500 comments.

The comments received were categorised according to sentiment as neutral, positive or negative towards ePI. The majority of comments were neutral (75%), 17% of comments were positive and 8% were negative.



3. Methodology

The working group reviewed and analysed all the comments received during the consultation. Comments were categorised as follows:

- **Noted:** these comments were noted for information;
- **Noted for implementation:** these comments were not directly relevant to the 'key principles', which are intended as a guideline, and related instead more specifically to implementation of ePI. They were noted for other planning and documentation related to implementation;
- **Out of scope:** these comments were considered as being out of the scope of the current work;
- **Already included in principles:** these comments made points that were already mentioned in the 'key principles' and were often underlining support for certain aspects;
- **Not accepted:** these comments included suggestions for text changes that were not considered appropriate or comments that were not aligned with the EMA-HMA-EC thinking on the ePI initiative. Although not accepted, nevertheless the comments were noted;
- **Text changed:** the text of the 'key principles' was updated to reflect points made in these comments. Many contributors requested clarification or further explanation on some aspects of the 'key principles' and the text was updated accordingly. Text changes were also made to reflect points detailed below.

4. Main points raised during the consultation

4.1. Scope of ePI

The 'key principles' define ePI as an electronic version of the statutory product information for medicines (i.e. SmPC, PL and labelling).

Contributors requested that the scope of ePI be widened to include additional content such as photos of medicines, risk minimisation material and Direct Healthcare Professional Communications (DHPCs).

However, these materials are considered to be outside the scope of the current ePI initiative, and it is considered that the scope should remain restricted to the authorised PI to ensure harmonised progress. This does not preclude creation of electronic formats for these materials outside of the ePI initiative. The availability of additional material in electronic format will complement ePI and increase the possibilities for dissemination and display of information on medicines to the public.

4.2. Improvement of PI content

The EMA action plan, based on the European Commission's recommendations on product information, identified several wide-ranging actions relating to enhancing readability, improving patient input in development and testing, promoting best practices and developing an electronic format. The electronic format (ePI) is the most pressing priority out of the actions from a public health perspective as it will ensure patients have timely access to up-to-date information and coordination among the many initiatives ongoing in the EU. The 'key principles' specifies that creation of an electronic format does not involve any change to the content of the PI. Contributors proposed that actions related to improving the PI content should be carried out in parallel or in preference to work on ePI.
Given resource constraints and business continuity planning during the relocation of the Agency, it has been necessary to postpone many activities of the Agency's work. For these reasons, ePI was prioritised and it has not been possible to progress other actions in the EMA action plan. However these will be pursued once resources are available.

4.3. Efficiencies for regulatory systems

The draft 'key principles' outlined benefits of ePI for public health including expanding access to the PI and improving accessibility. Potential benefits for regulatory systems were not mentioned in the draft.

Contributors suggested that the potential for ePI to enable efficiency gains in regulatory processes should be included as a key principle, as such gains should guide future implementation of ePI in addition to public health gains.

Additional key principles were added under a new heading 'Efficiency gains for regulatory systems'. These describe how ePI could improve the performance of regulatory procedures following implementation and could become a rich source of information on medicines for a wide variety of research.

4.4. Complementing paper package leaflet

The 'key principles' state that ePI will be developed and implemented in line with the legislation in force. This implies that ePI will not supersede or negate the requirement of the legislation to include a PL in the packaging of all medicines.

Contributors expressed differing views on this point. Several contributors proposed the replacement of paper PI with ePI (with an option to print out where needed) citing environmental benefits, facilitating access for small markets, facilitating management of shortages, use in settings such as hospital where patients do not handle their medicines, and the resources involved in maintaining both paper and ePI systems. On the other hand, many contributors stressed their support for ePI as a complement to paper, due to a wide range of digital literacy levels and variations in access to digital tools and internet among patients and consumers.

Since the ePI initiative will work within the current legislative framework, consideration of replacement of paper PL with ePI is outside the scope of this initiative. In addition, the intention is not to limit access to PI, but instead to expand the formats in which PI is available, enabling easier access by patients / consumers to the PI in their preferred format, be that paper or electronic format.

4.5. Use of ePI for promotional purposes

The updated 'key principles' state that ePI is intended for the delivery of the full and complete regulator-approved medicine information, and that PI will not be used for delivery of promotional information.

Contributors expressed concern that ePI would enable use of ePI for promotional purposes or delivery of only selected sections of the PI, giving an incomplete and possibly promotional view of the information on the medicine.

The 'key principles' were updated to clarify that ePI must comply with the applicable EU legislation, which strictly regulates the content of PI and excludes any element of a promotional nature. As is the case for the currently available PI, the ePI shall be published in full, without any amendments in the text or additional content.

5. Next steps

The final Electronic product information for human medicines in the EU – key principles are published on the EMA website. All the comments received in the consultation are also published in a partially anonymised PDF format as well as a categorised list in Excel format (see 'Methodology' above for details of categorisation).

Following the consultation, analysis and implementation of updates, the final 'key principles' have been adopted by HMA and by EMA's Management Board. In addition, a roadmap for implementation has been created and work is ongoing on project management aspects, including ongoing stakeholder consultation and options for resourcing. Updates will be published as appropriate on the EMA website.

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