

Report on public consultation on EU ePI Common Standard

Summary of comments received and next steps



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1. Background of consultation

A report from the European Commission (EC) in March 2017, and subsequent EMA [action plan](#), identified the development of an electronic format (ePI) as an action to improve medicines' product information (PI) to better meet the needs of patients and healthcare professionals (HCPs). Stakeholder consultation on ePI led to the publication of [key principles](#) to guide development and use of ePI in the EU. The scope of this work is all centrally and nationally authorised medicines in the EU.

Throughout 2021, EMA, national competent authorities and the European Commission conducted an ePI set-up project to develop a EU ePI Common Standard. A EU ePI Common Standard refers to the technical features of ePI agreed by regulators and stakeholders. The documentation for the draft EU ePI Common Standard was the subject of a public consultation (June to July 2021).

The consultation was carried out on the following documents:

- ePI API Specification (PDF) and the associated ePI API service list (Excel);
- A FHIR XML template based on the Quality Review of Documents (QRD) template for human medicines;
- An instance of an ePI sample message provided in XML and HTML, along with a sample XSL transformation.

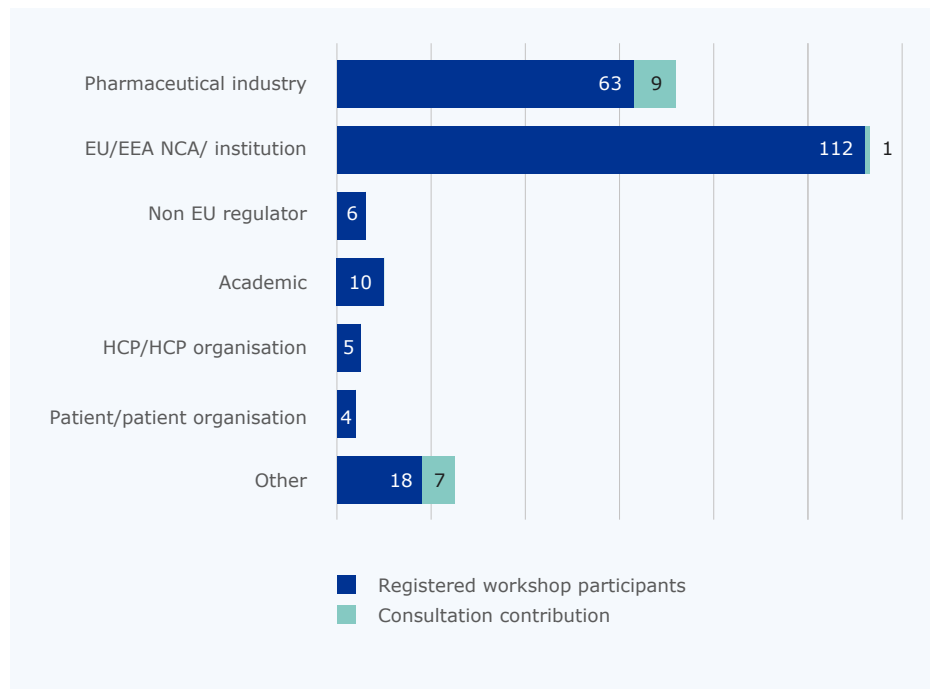
To facilitate stakeholder consultation, EMA hosted [virtual workshops on 5-8 July](#) to inform on the proposed standard and explore its future use. Feedback from the workshops contributed to ensuring that the adopted standard meets the needs of future users. In addition to comments received during the workshops, consultation feedback was also collected via a survey and in writing.

The comments received during the consultation were reviewed by the ePI project team, and taken into account for the finalisation of the abovementioned documents. The comments are also taken into consideration for the ePI roadmap and for future implementation of ePI in the EU.

2. Contributions

In total, 17 contributors responded to the consultation by survey (see Annex for the content of the survey) or by email to ePI@ema.europa.eu. In addition, comments provided during the virtual workshops were documented. The affiliations of the contributors and workshop participants are shown in Figure 1. Contributors in the category 'Other' included standards organisations, companies, IMI project representatives, publishers, medicines information centres and not-for-profit organisations. Most contributions received consisted of multiple comments on different aspects of the draft standard. Dividing contributions into individual comments resulted in around 200 comments.

Figure 1. Affiliation of ePI workshop participants and survey/email consultation contributions.



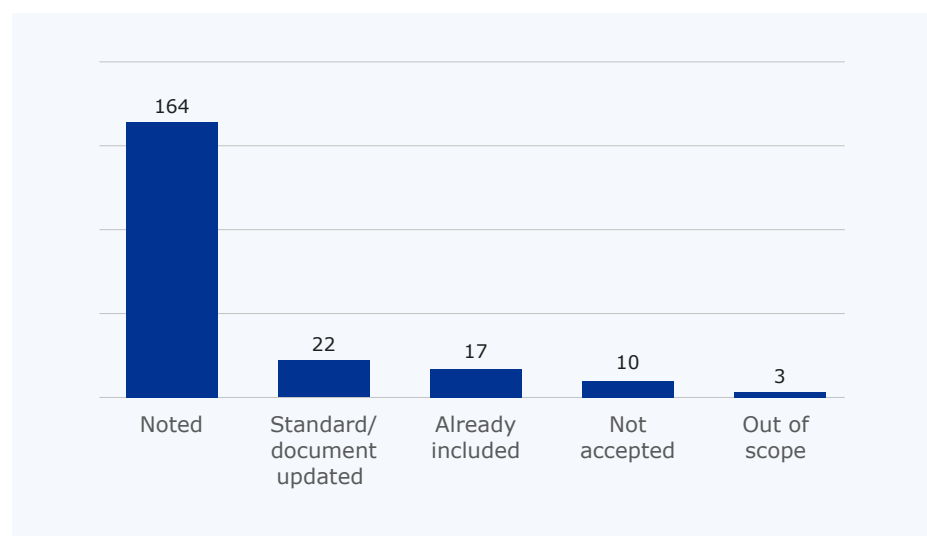
3. Methodology

All the comments received during the consultation were reviewed by the ePI project team. A response to each comment is provided in the file '[EU ePI Common Standard - categorised comments received following public consultation \(partially anonymised\)](#)'.

In addition, comments were categorised based on the action taken in response to the comment, as detailed below. Distribution of comments into these categories is shown in Figure 2.

- **Noted:** this category is used where these comments were noted by the ePI team for consideration in ongoing or future work. It is also used where the comment is a question or request for clarification that is responded to;
- **Standard/documentation updated:** the FHIR XML template or the ePI API specification were updated to address these comments;
- **Already included:** these comments made points that were already included in the draft EU ePI Common Standard;
- **Out of scope:** these comments were considered as being outside of the scope of the current work;
- **Not accepted:** these comments included suggestions that were not aligned with the EMA-HMA-EC thinking on the common standard. Although not accepted, nevertheless the comments were noted.

Figure 2. Distribution of comments into categories.



4. Main points raised during the consultation

Full details of the contributions received in the public consultation and responses are published in [`EU ePI Common Standard - categorised comments received following public consultation \(partially anonymised\)`](#).

The main points raised are summarised below.

4.1. Data granularity

Contributors noted that incorporation of increased granularity of data in ePI will enable advanced use cases.

The granularity of the EU ePI Common Standard is at level of QRD template headings, and the ePI is annotated with a link to the medicinal product in SPOR. This enables browsing ePI by section and combining the SPOR API and the ePI API to produce business value.

Increasing the granularity of the information in ePI to support additional use cases is part of the future vision for ePI and inclusion of additional standardised data in ePI in the future is feasible.

4.2. Decoupling of style and content

Contributors expressed the need for separation of ePI content from styling.

ePI examples used in the exploratory workshops contained styling information remaining after the ePI generation process. This is because the ePI generation was carried out in the context of a proof-of-concept exercise. It is envisaged that style aspects will be separate from content when ePI is implemented, with only styling necessary for understanding of the product information included (e.g., tables). The possibility of provision of a recommended style sheet will also be considered.

4.3. Filtering ePI and incremental update of local ePI

Contributors expressed the need for the functionality to filter ePI data by product, document type, languages etc. In addition, support is requested for incrementally updating local copies of ePI data.

Filtering and incremental update will be investigated in future work. EMA has already submitted change requests to HL7 for searches on language, text and by section and support to searches and update of local ePI will be part of future development.

4.4. Challenges of generating ePI from existing Word documents

Contributors provided feedback on important considerations in conversion of Word or PDF documents to ePI.

In the proof-of-concept prototype developed as part of the ePI set-up project, ePI was generated from existing product information documents in Word format. As the generation of ePI was carried out in the context of a proof-of-concept exercise, several aspects, such as generation of tables in ePI, were not optimised. Providers with extensive experience in this field provided valued feedback on this topic.

4.5. Alignment with other projects and FHIR versions

The importance of aligning ePI developments with those of related projects and systems was highlighted by contributors. In addition, the need for coordination of FHIR versions used by related systems was underlined.

ePI has significant synergies, dependencies and overlap with the SPOR master data system and the Digital Application Dataset Integration project (DADI) for electronic application forms, and these will be taken into account during development. FHIR versioning will be controlled and communicated, in coordination with and taking into account other dependent EU telematics systems.

4.6. Future business process

Many comments from contributors were related to future business processes (e.g., quality control, access and authentication), documentation (e.g., authoring guide, implementation guide) for ePI, integration with other systems such as procedure management systems, or related developments such as use of barcodes to access ePI.

Although these comments are outside the scope of the current consultation, which is limited to the documents listed in '[1. Background of consultation](#)', the comments were useful and noted for consideration in ongoing progress towards ePI implementation.

4.7. Editorial and technical aspects

Comments were submitted on technical features of ePI and on editorial aspects of the ePI API Specification document.

Details and responses are provided in the '[EU ePI Common Standard - categorised comments received following public consultation \(partially anonymised\)](#)'. Updates to the ePI API Specification included addition of a table to clarify how FHIR resources are used by ePI and streamlining of naming within the document.

5. Next steps

The ePI team wish to thank partners and stakeholders for their active participation in the workshops and valuable consultation contributions.

Following the consultation, analysis of feedback received, and implementation of updates, the final EU ePI Common Standard was adopted by the EU Network Data Board on 22 September. The updated EU standard is now [published](#).

All the comments received in the consultation are published in a partially anonymised [categorised list in Excel format](#) (see 'Methodology' above for details). A roadmap will be shared with stakeholders in due course. Updates on the ePI initiative will be published on an ongoing basis on the [EMA website](#).

Annex

Consultation survey

Profile

This questionnaire should be completed once you have reviewed the published documentation for the standard (available here: <https://github.com/EuropeanMedicinesAgency/ePI-consultation>), which includes:

- xml, xsl and html files
- Draft ePI API specification and draft ePI API service list

First name:

Surname:

Your email:

Your affiliation:

- Member of the public
- Patient/carer
- Healthcare professional
- Academic
- Pharmaceutical industry
- Health Technology Assessment Body
- EU/EEA national competent authority
- European Institution (e.g. European Parliament, European Commission)
- EU agency
- Non-EU regulatory authority
- Other (please specify)

Please provide the name of your organisation (or state 'non-applicable')

Your country of residence:

Documentation

Indicate the documentation you would like to comment on (select all that apply):

- ePI API specification
- xml, xsl, html files

Indicate the ePI API specification section you would like to comment on (select all that apply):

- Document Purpose
- Scope
- Introduction
- Specification
- Resource structure
- REST services
- Resources
- About this document
- ePI API service list

Comments

Detail the document line number, your comment, rationale, and any proposed changes for section 1. Document Purpose:

Detail the document line number, your comment, rationale, and any proposed changes for section 2. Scope:

Detail the document line number, your comment, rationale, and any proposed changes for section 3. Introduction:

Detail the document line number, your comment, rationale, and any proposed changes for section 4. Specification:

Detail the document line number, your comment, rationale, and any proposed changes for section 5. Resource structure:

Detail the document line number, your comment, rationale, and any proposed changes for section 6. REST services:

Detail the document line number, your comment, rationale, and any proposed changes for section 7. Resources:

Detail the document line number, your comment, rationale, and any proposed changes for section 8. About this document.

Detail your comment, rationale, and any proposed changes for ePI API service list.

Detail your comment, rationale, and any proposed changes for xml, xsl, html files.

General comments

Enter any general comments you may have:

Thank you very much for your contribution.

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Send a question: www.ema.europa.eu/contact

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