7 June 2021
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European Medicines Agency

Open consultation

Draft EU Common Standard for electronic product information for human medicines (ePI)

1. What is ePI?

EU Common Standard for electronic product information (ePI) is authorised, statutory product information for EU medicines (the summary of product characteristics [SmPC, intended for healthcare professionals], labelling [outer and inner packaging information] and package leaflet [PL, for patients / consumers]) in a semi-structured format created using the EU Common Standard. ePI is adapted for electronic handling and allows dissemination via the web, e-platforms and print.

2. Consultation

EMA, national competent authorities and the European Commission are conducting an electronic product information (ePI) set-up project to develop an EU Common Standard for ePI.

An EU Common Standard for ePI refers to the technical features of ePI to be agreed by regulators and stakeholders. The documentation for the draft EU Common Standard is currently the subject of an open public consultation.

To facilitate stakeholder consultation, EMA hosted half-day virtual workshops on 5-8 July to inform on the standard and explore its future use. Feedback from the workshops will contribute to ensuring that the adopted Common Standard meets the needs of its future users, confirming they can access, view and disseminate product information in electronic format, ePI.

[1] The document was updated on 20 July 2021 to fix a broken link and to note that ePI workshops took place on 5-8 July 2021.

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The consultation is being 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 is provided in XML and HTML, along with a sample XSL transformation.

Consultation feedback is collected via this survey.

3. ePI FHIR message template

The objective of the ePI (FHIR) template is to be used by template engines to transform PI information, in structured or semi-structured format (e.g. JSON, CSV, etc), to an ePI FHIR message. Items in the template, marked with "${}" will be replaced by Product Information (PI) data entities.

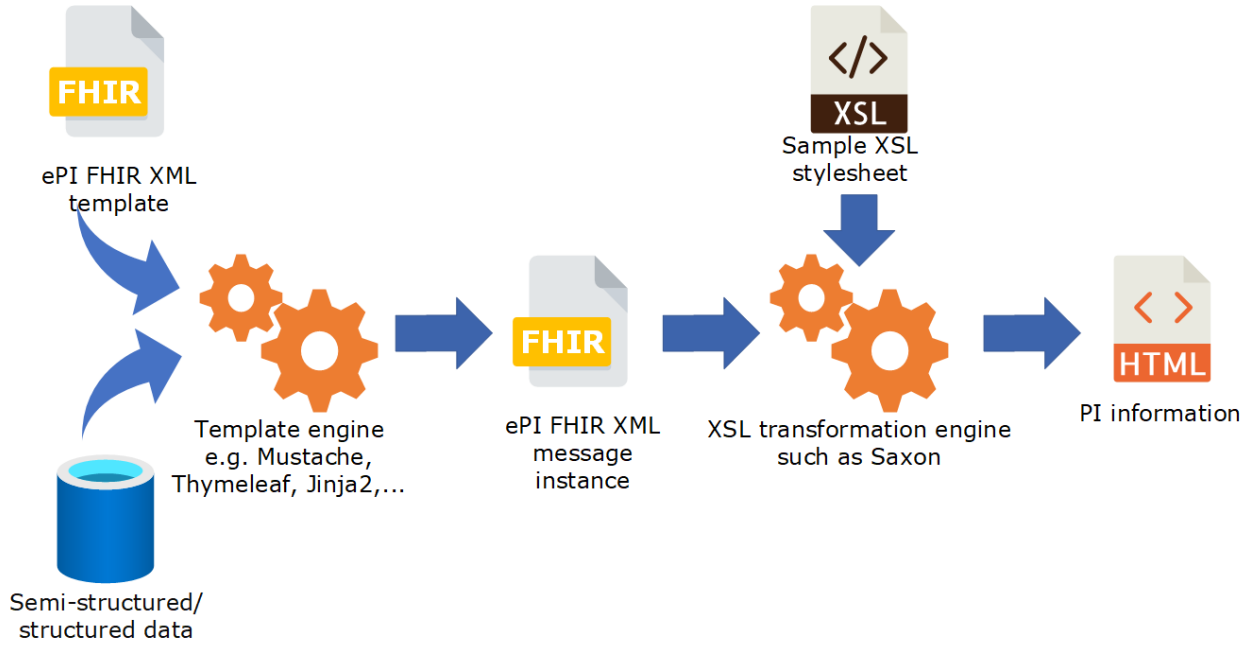

Figure 1. Transformation of PI information.

The resulting ePI XML message contains a FHIR resource, a Bundle of Bundles, each of which is a document having a Composition, and supporting resources.

Please refer to the ePI API specification for more information on the structure for the ePI FHIR message.

For demo purposes, please find here an XSL stylesheet, converting ePI messages to HTML. One example of an XSL transformation engine can be found here.

4. Workshops

The Information Workshop aimed at stakeholders and partners took place on 5 July. The Exploratory Workshops aimed at technical participants with knowledge of development languages and REST API took place on 6-8 July.

5. Contact

For further information or clarifications please contact ePI@ema.europa.eu.