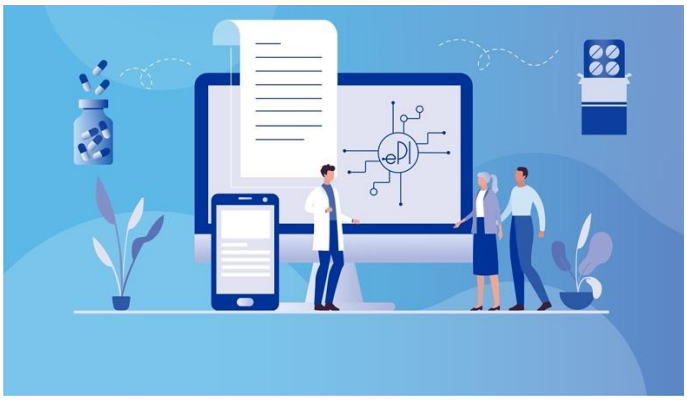
IATF ePI –EMA ePI common standard consultation



General comments

The pharmaceutical industry fully supports the provision of comprehensive, accurate and up-to-date regulator-approved information on medicinal products, both for patients and healthcare professionals (HCPs) and EMA/HMA's conclusion that there is a need to explore alternative innovative pathways of disseminating information in electronic format.

The Inter Association Taskforce ePI believes that public health could benefit enormously from a coherent and consistent ePI implementation across the EU. Considering new advanced technologies, we could and must go beyond the current scope proposed by the EMA key principles[1].

In this context, we welcome initial steps of EMA to progress the implementation of electronic product information (ePI) as defined by the EMA/HMA ePI Key Principles[2] (published January 2020).

The experience gained during the consultation process and with the proof-of-concept (PoC) are supposed to influence the ePI project roadmap and the implementation thereof in an agile manner. Given the new telematics governance structure, where an agile SAFe method will be piloted by the EMA and NCAs for ePI, DADI and PMS, the industry requests for the EMA to specify how the ePI programme including the deliverables of a roadmap will be implemented into such methodology. As transparency is at the forefront of being agile, Industry would like to see a visual overview of the future telematics ecosystem for the network, including ePI creation tool, SPOR PMS, DADI and an efficient regulatory business process (TOM), which factors in submission, validation, assessment, decision and dissemination. Clear assignment of responsibility is required to clarify the accountability and liability for each step of the ePI process; in particular for the release of the ePI final content that will be publicly available.

To achieve the ambition as laid out in the EMA/HMA ePI Key Principles, the Inter Association Taskforce ePI (IATF ePI) is supportive to a stepwise implementation in a collaborative manner given necessary transparency and clear understanding for every single deliverable is given. Each single step of the roadmap is recommended to be accompanied by a clear charter (agile backlog) explaining what is in- and out-of-scope of the value added milestones that make up the roadmap and how it relates to the broader context of the overall ambition for ePI and related telematics projects.

For example, being consulted on the functionality of the API and the ePI standard we consider essential information to be missing, particularly on the context the API is to be explored in. Is the purpose to assess the API in a post-approval step for publication of product information to a public audience only or is the API designed to deliver additional steps in the regulatory business process? Our response may fall short and not

[1] https://www.efpia.eu/media/589590/electronic-product-information-from-principles-to-actions.pdf

[2] https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf

address all expected aspects given the overall objective is not clear. It is highly recommended for the roadmap and future consultation to provide more context, e.g. the positioning in the regulatory business process, to get the most valuable feedback.

As part of the workshops a proof-of-concept (PoC) for a conversion tool (Word - html - FHIR) has been demonstrated compared to the ambition given in the EMA/HMA ePI Key Principles[2] describing the ambition for a creation tool that builds on existing data, e.g. captured in SPOR. Considering the presented purpose and scope of the API, this could be considered a failure of the PoC. Industry would like to understand how the ePI project will take lessons from the existing structured product information which are in place at a national level (Belgium, Spain, Germany, Sweden) and leverage the lessons learnt for Centrally Authorized Products. The roadmap is expected to deliver more clarity on the evolution of the existing conversion tool to an ePI Creation Tool.

As part of the workshops, it has become apparent that industry stakeholders couldn't access SPOR data in a similar way compared to other experts. To ensure constructive feedback in an agile environment equality to information is needed for all stakeholders, during the consultation and implementation process.

Managing structured data in high quality is key to a successful implementation of ePI in the European network and wherever possible SPOR resources should be (re-)used in ePI. For example, substances form an important part of the product information and correct spelling could be ensured by using validated information from SPOR PMS and SPOR SMS instead of free text. This would further enhance search capabilities of ePI.

Given only read and search has been tested, the process to exchange ePI and its related bundles is unclear in the context of current discussions in the DADI, SPOR and IRIS activities. Besides providing a roadmap, standard and prototype as deliverable of the ePI setup project, an additional deliverable providing more clarity on the overall ambition and relationship to existing initiatives is expected.

FHIR resources are used across various projects (including SPOR, DADI) in the EU regulatory network and keeping all projects in sync will be key for a sustainable framework. A clear governance structure and alignment with the HL7 FHIR initiative is proposed including important steps such as balloting of necessary FHIR resources, release planning for the ePI API and guidance for mandatory implementations.

We understand the focus of the consultation is on the API and the EU ePI standard and not all aspects are yet delivered. As additional deliverable, we consider essential the development of an additional ePI technical authoring guide (incl. guidance for mark up, creation of tables, etc) to ensure product information are already authored having the API and the ePI standard in mind and consistency and first-time-right creation facilitates the conversion/creation of ePI. It is worth noting that the current FHIR structure is not supporting current accessibility features, as laid out In the Standard WCAG 2.1 (Web Content Accessibility Guidelines).

Converting docx to html might introduce errors and discrepancies in the converted content, how do you envision to put in place QC to ensure the source is identical to the output?

Timely progressing of ePI implementation while considering the flexibility needed in the European network and granularity in implementation steps is key for longer term sustainability. This includes clarity on the roles of the various stakeholders alongside the current and future regulatory business process and during implementation of ePI. An EU Implementation Guide elaborating on the concept of ePI, structured, unstructured and re-usable elements as well as specifying the business rules should be provided.

Free access to trustworthy information will be key for the audience and access to the API should be consistent with other EU implementations and consider the access of group of users, individual users and the role of the users.

The IATF ePI is supportive to the implementation of ePI and is willing to help bringing the industry voice to the discussion.