Contribution to the consultation on Electronic Product Information

M.T. Carrasco Benitez - 7 July 2021

Overview

This is a contribution to the open public consultation [OPC] on the *EU Common Standard for ePI*, though no direct comments to the consultation documents. It is an alternative proposal; details in `http://epi.red`. One should aim at having a usable standard in a **few months**.

Warning

The Product Information Management project (PIM) ran for over ten years without achieving any results at the end [POD][PC]. The current round of efforts has been going on for at least four years [RPI][FCR][EAP][KP].

Scope and governance

The scope of a new initiative for Electronic Product Information (EPI) should be the **whole world**, not just the European Union (EU). The EU might focus in solving the requirements of the EU, but the framework must allow the incorporation of non-EU entities.

To guide the initiative, there should be a permanent independent *Foundation for Electronic Product Information* open to all comers. The Foundation will be a nonprofit organisation, essentially a web site: no building or staff; people participating will typically be working for another organisation such as European Medicinal Agency (EMA). The computer hosting and similar materials should be provided by the collaborating entities; hence, the direct budget is practically nil.

There must be a proper governance. To start with, it should be sufficient to have a director, board and coordinators for working groups.

Technology

Keep it as **simple** as possible. Techniques should be accessible to most people, particularly non-IT experts as many participants come from other fields such as pharmacy or medicine.

The adopte solution must allow the preparation of product information by clerical staff: offline just with a template and a basic editor such as Notepad. There should be no dependence on online systems, specialised bespoke systems, or even an XML editor. The technology stack should minimise dependencies, such as from HL7 or others.

To start with, just focus on one item: the **data format** of the Summary of Product Characteristics (SPC). In essence, to code the Notice to Applicants [NA] and the Quality Review of Documents [QRD]. Other items would come later: package leaflet (PL), transport, updates, electronic signature, etc. Multilingualism must be an integral part from the very beginning.

One should follow common practices in standardisation such as Internet Engineering Task Force [IETF] or similar organisations. In particular, the use of mailing lists [ML]: having only meetings every few months does not work as there are lots of details to discuss.

Data format standard

It is an exchange data format: *producers* create it how they want; *consumers* absorb it how they want. Though, the standard must be gracious to produce and consume. It should be easy: to produce it by human and machines; and to consume it without specialised systems. To start with, it should

only contain what it is strictly needed for a usable functioning standard.

The proposed standard has two parts: *container format* [CF] and *document type definition* [DTD]. A container format is required to pack all documents: a zip file containing a specified directory structure and navigation friendly when unzipped [CF][XDO]. The DTD is the coding of QRD results from prose to formal notation. Documents are in XML with CSS; no transformation into HTML [WPS][WPX], hence avoiding more complex technologies.

Scalable Vector Graphic [SVG] could be added later to facilitate language neutral data from a single source, for prose and graphics.

Build an example

To verify that the proposed standard works, the product information of an existing product should be recreated, simultaneously with the creation of the standard. One of the tests should be to check how easy it is to change trivial non-medicinal data such as addresses.

Generation of Electronic Product Information Documents (Ged) is a computer system that generates the product information in any number of languages from text tables [GED]. The core work is completed: programs, architecture, XML template and DTD. Most of the work left is simple: fill the tables and refine the lower children in the XML tree. Ged would help with the development of the standard proper as the DTD validates the documents; and with building the example as it generates all the 26 linguistic versions.

A follow up project should be the transformation of all the product information of centrally authorised products, or at least significant number; this would be quite mechanical. In addition to fully prove that the new standard for ePI works, it would be a large set of fine granularity data that would be a great asset for further work such as cross-checking.

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References

[CF] Container format
https://en.wikipedia.org/wiki/Container_format_(computing)

[DTD] Document type definition
https://en.wikipedia.org/wiki/Document_type_definition

[EAP] EMA action plan related to the European Commission's recommendations on product information
https://ec.europa.eu/health/sites/default/files/files/committee/pharm-3ii_ema-update.pdf

[FCR] Follow-up to Commission's Report on Product Information Leaflets and related activities
https://ec.europa.eu/health/sites/default/files/files/committee/81meeting/pharm_3ii_epi_en.pdf

[GED] Generation of Electronic Product Information Documents (Ged), computer system to generate product information
http://epi.red/ged

[IETF] Internet Engineering Task Force
http://ietf.org

[KP] Electronic product information for human medicines in the EU: key principles, A joint EMA–HMA–EC collaboration
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/electronic-product-information-human-medicines-european-union-key-principles_en.pdf

[ML] Mailing list of the IETF HTTP Working
https://lists.w3.org/Archives/Public/ietf-http-wg

[NA] Guideline on Summary of Product Characteristics (SmPC), Notice to Applicants, September 2009
https://ec.europa.eu/health/sites/default/files/files/eudralex/vol-2/c/smpc_guideline_rev2_en.pdf

[OPC] Open consultation - Draft EU Common Standard for electronic product information for human medicines (ePI)
https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/draft-eu-common-standard-electronic-product-information-human-medicines-epi_en.pdf

[PARDOC] Multilingual parallel documents
http://dragoman.org/pardoc

[PC] European Medicines Agency closes PIM project, 2011-03-28
http://web.archive.org/web/20130830151827/http://web.archive.org/screenshot/http://pim.ema.europa.eu

[POD] PIM Open Day, 2000-09-22
http://web.archive.org/web/20020104195034/http://esubmission.eudra.org/pim/openday

[QRD] Product-information annotated template, Quality Review of Documents, February 2021
https://www.ema.europa.eu/en/documents/template-form/qrd-product-information-annotated-template-english-version-102-rev1_en.pdf

[RPI] COM(2017)135 - Report on current shortcomings in the summary of product characteristics
https://ec.europa.eu/transparency/documents-register/detail?ref=COM(2017)135&lang=en

[SVG] Scalable Vector Graphic
https://www.w3.org/Graphics/SVG

[UC] Unicode Consortium
http://unicode.org

[W3C] Web Consortium
http://w3c.org

[WPS] Wonderpill, with CSS, example of product information generated by Ged
http://epi.red/ged/doc/en.xml

[WPX] Wonderpill, without stylesheet, , example of product information generated by Ged
http://epi.red/ged/tree/en.xml

[XDO] Xdossier, M.T. Carrasco Benitez, Expired Internet-Draft, 2004
https://datatracker.ietf.org/doc/html/draft-carrasco-xdossier-04