REFERENCING THE ePIL

Document History

Version	Date	Reason
0.1	19/3/2025	First draft
0.2	25/03/2025	Adapt to support multiple documents for a same vaccine code
1.0	29/03/2025	First release

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1 Object

This document exposes the method enforced within the EUVABECO project to bind the NUVA codes representing the administered vaccines with the relevant official documentation. It corresponds to the step “Defining the Lookup mechanism” in the workflow exposed in the EUVABECO ePIL draft implementation plan.

2 Data model

Endorsing a document for a vaccine belongs to a health jurisdiction.

Each health jurisdiction may be specific in:

- The list of documented vaccines.
- The type of the endorsed documents.
- The languages of the endorsed document.
- The location where the document can be retrieved (URL).

Health jurisdictions are typically countries but may also be regions (Catalan documents may be proposed in Catalonia but not required for all of Spain). They are identified with:

- For countries: the ISO 3166 alpha-3 code (BEL, GRC, LVA, …)
- For regions or federated states: the ISO 3166-2 code (DE-SL, GR-M, …)
- For the European Union: EUE

The notion can be extended to reliable non territorial sources, for which the code will be a dedicated one prefixed by XX-.

In EUVABECO, only two types of documents are identified:

- Patient Information Leaflet (ePIL)
- Summary of Product Characteristics (SmPC)

For a given set of a jurisdiction, a vaccine code, a type of document and a language, there is generally only one related document. Yet, it can happen than several documents are present for this combination, for example when a same product is proposed with prefilled syringes or bulbs of solvent. To support this, the vaccine code is supplemented by an index, although in most cases only the value 1 will be used. A descriptive label is attached to each such index.

The overall data model can thus be illustrated as follows:

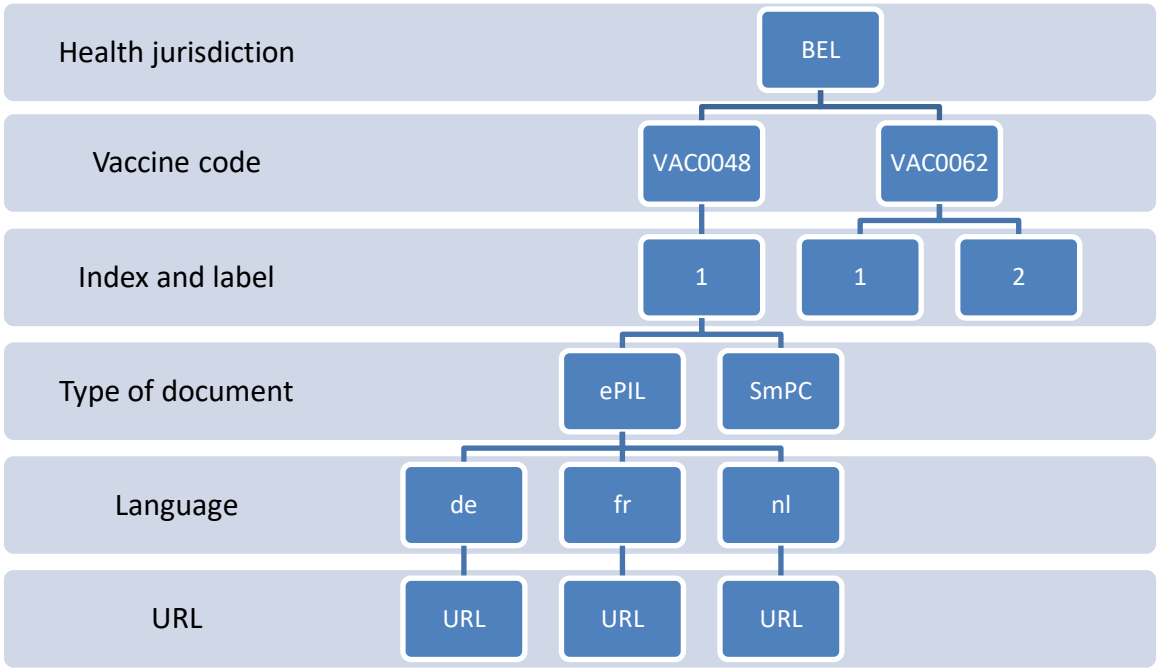

Figure 1- Data model

The URL represents the location for the approved document. Yet, within the EU the same documents apply for all centrally approved products. To support this, as well as the referencing of documents curated by another health jurisdiction, URLs can also be redirections to another health jurisdiction, where the real document URL will be retrieved using the same qualifiers of vaccine code, type of document, language, and when exceptionally needed an index across similar documents.

When the index is omitted, it is implicitly set to 1. Thus URL /BEL/VAC0048/ePIL/nl refers to the same document as /BEL/VAC0048/1/ePIL/nl.

3 Representation

3.1 Mapping file

The mapping for each health jurisdiction is represented by a structured file in YAML format, named XXX.yml, where XXX is the code for the jurisdiction. This simple format, readable both by humans and by machines, allows to track directly the changes between versions.

The file consists of one entry per documented vaccine, matching the data model presented above, such as:

```
VAC0003:
  1:
    label: Avaxim 0.5 ml susp. inj. s.c./i.m. ser. préremplie
    ePIL:
      fr: https://app.fagg-afmps.be/pharma-status/api/files/xxx
      nl: https://app.fagg-afmps.be/pharma-status/api/files/xxx
      de: https://app.fagg-afmps.be/xxx
    SmPC:
      fr: https://app.fagg-afmps.be/pharma-status/api/files/xxx
      nl: https://app.fagg-afmps.be/pharma-status/api/files/xxx
```

A redirection entry would have a format such as:

```
VAC0010:
  1:
    label: HBVaxPro 40 µg/ml susp. inj. s.c./i.m. flac.
    ePIL:
      fr: https://epil.euvabeco.eu/EUE/VAC0010/ePIL/fr
      nl: https://epil.euvabeco.eu/EUE/VAC0010/ePIL/nl
      de: https://epil.euvabeco.eu/EUE/VAC0010/ePIL/de
    SmPC:
      fr: https://epil.euvabeco.eu/EUE/VAC0010/SmPC/fr
      nl: https://epil.euvabeco.eu/EUE/VAC0010/SmPC/nl
      de: https://epil.euvabeco.eu/EUE/VAC0010/SmPC/de
```

The server used for redirection (here https://epil.euvabeco.eu/) is left to the initiative of the submitting health jurisdiction.

A redirection server can also be used as a convenience system to access any referenced document.

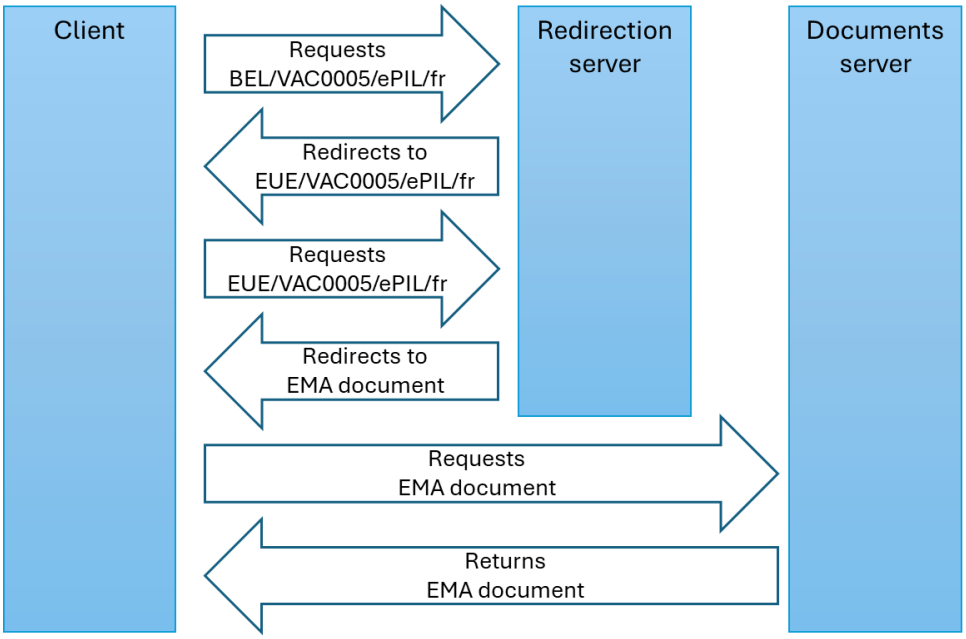

Figure 2- Using the redirection server

3.2 Repository

Within the EUVABECO projects, the mapping files are managed within the EUVABECO GitHub repository at https://github.com/EUVABECO/epil

Implementing partners for the ePIL are accredited to update this repository whenever they want to update the file for their jurisdiction.

Each publication triggers the creation of a release, including a change log and the creation of a configuration file for an Apache server implementing the redirection ((rewrite rules in a htaccess file). This configuration is uploaded every hour to the Euvabeco public server.

3.3 Usage

Implementing partners may:

- Fetch directly the YAML files from the repository and process them in their application. A JavaScript based example is demonstrated at https://epil.euvabeco.eu/list_epil and its code available in the same GitHub repository.
- Use within their implementation the redirection page exposed by the project at https://epil.euvabeco.eu/, complementing it with a health jurisdiction, a vaccine code, a document type and a language, such as https://epil.euvabeco.eu/BEL/VAC0041/ePIL/fr
- Download the Apache htaccess file and use it for their own redirection server.

They contribute to the mapping repository by updating the YAML file for their country in the GitHub repository.

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