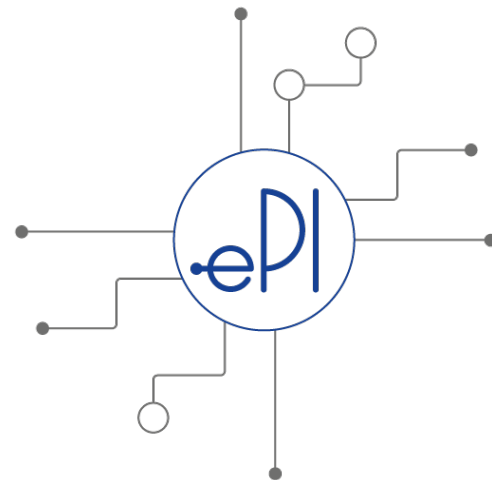


Description and demo of ePI API

Exploratory Workshop on electronic Product Information (ePI)

Achilleas Voutsas
Platform Architect, EMA



Contents

ePI conceptual model



ePI's API & demo



Annex

- Product Information landscape in EU
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- ePI FHIR API
- Useful links
- Demo

- ePI logical data model
- ePI FHIR resources and key attributes





ePI conceptual model

ePI, FHIR and SPOR
key entity description



ePI's API & demo

- ePI FHIR API
- Useful links
- Demo



Annex

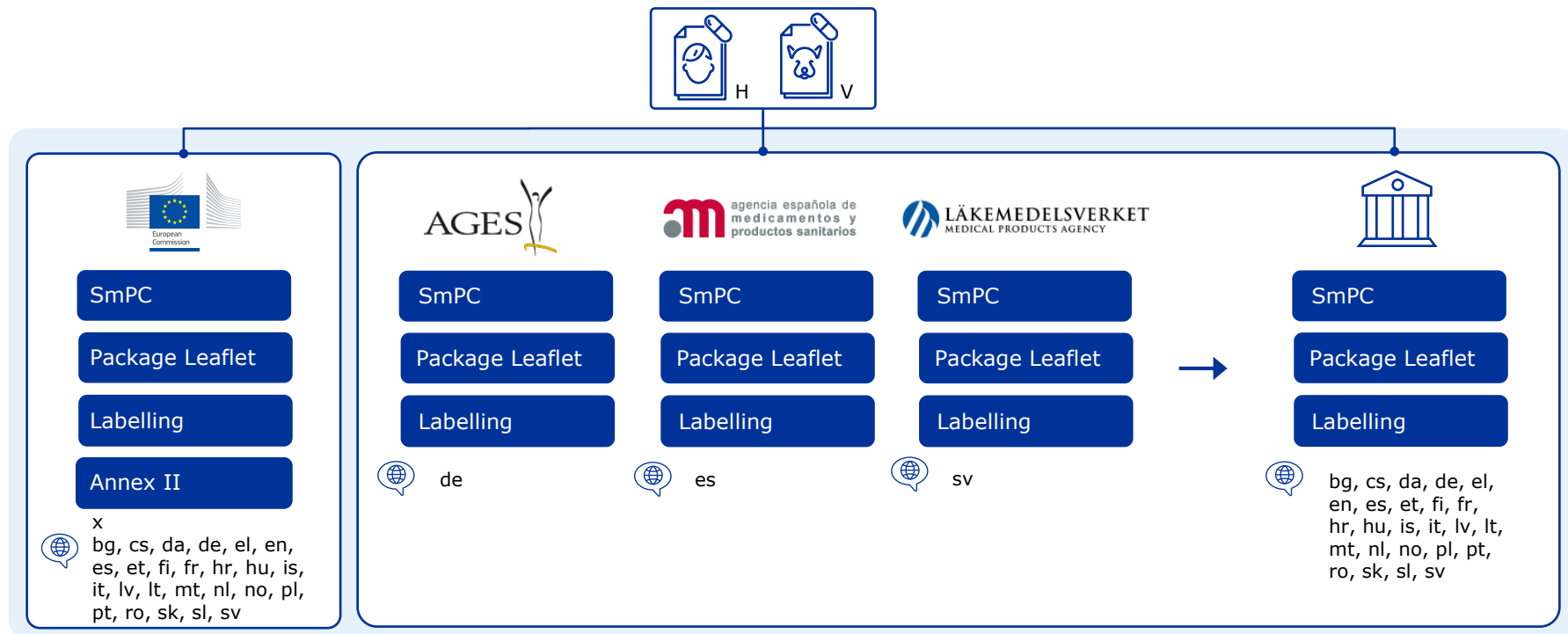
- ePI logical data model
- ePI FHIR resources and key attributes





ePI CONCEPTUAL MODEL

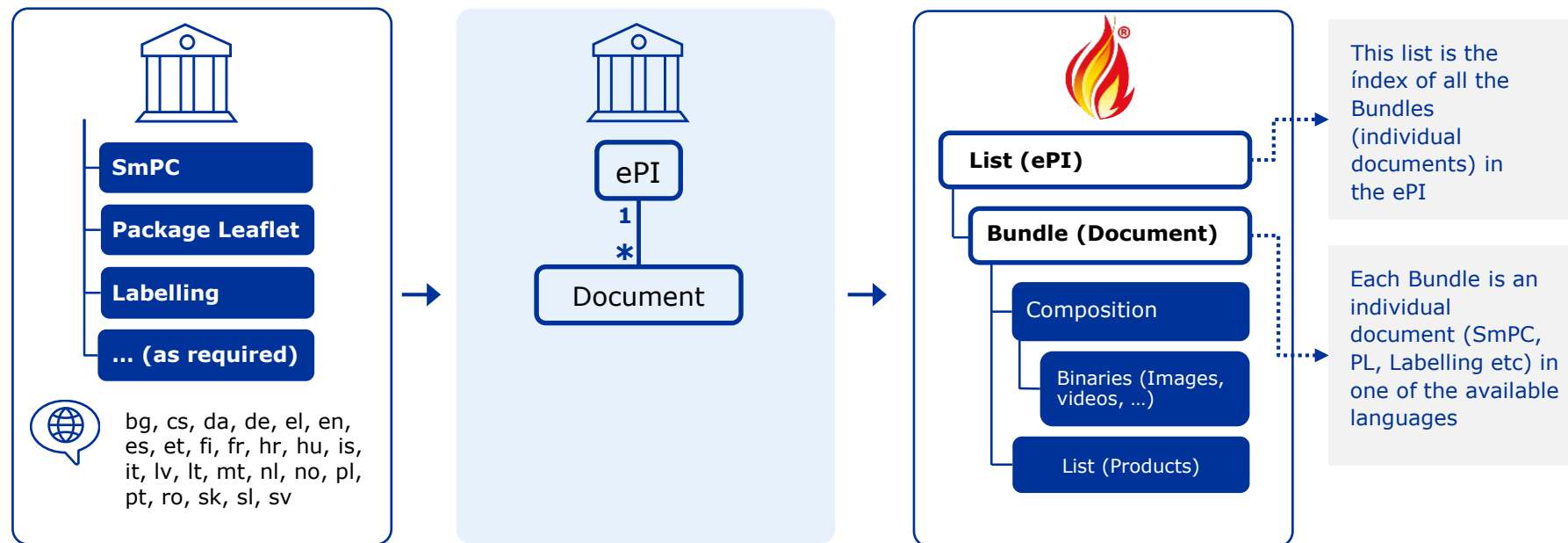
Product information landscape in EU



ePI CONCEPTUAL MODEL

How to describe ePI using FHIR®

*"**ePI** is authorised, statutory product information for medicines (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured ..."*

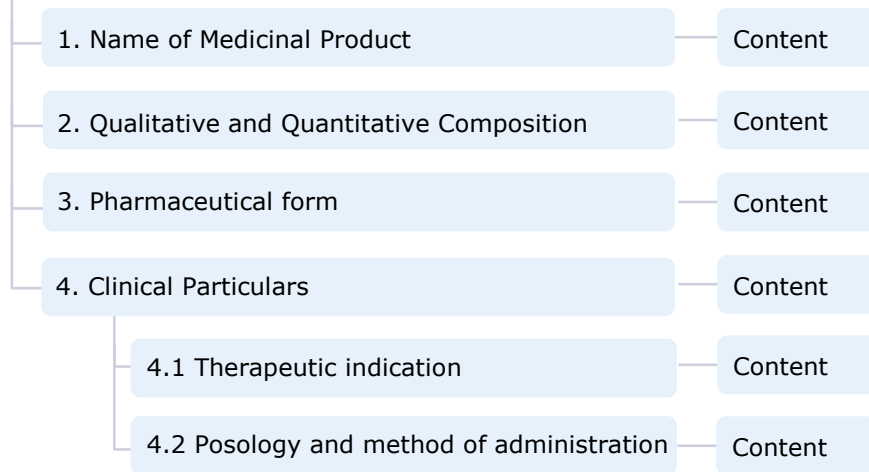


ePI CONCEPTUAL MODEL

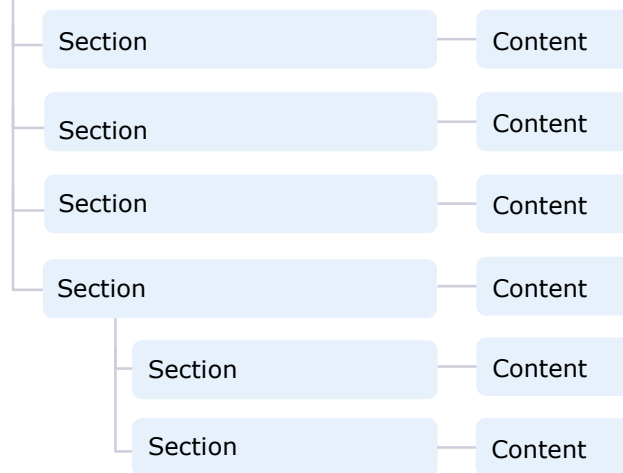
QRD representation in FHIR

Hierarchical support in FHIR [Composition/Section](#)

PI Document (SmPC)

SmPC

ePI FHIR Bundle (SmPC)

Composition

ePI CONCEPTUAL MODEL

ePI user of FHIR Composition

Composition

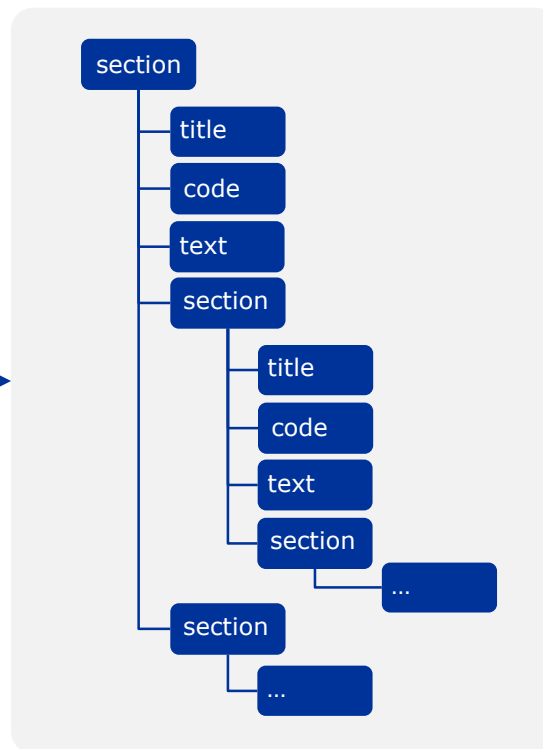
Binaries (contained)

MAH – OMS ID (author)

Title

Content (section)

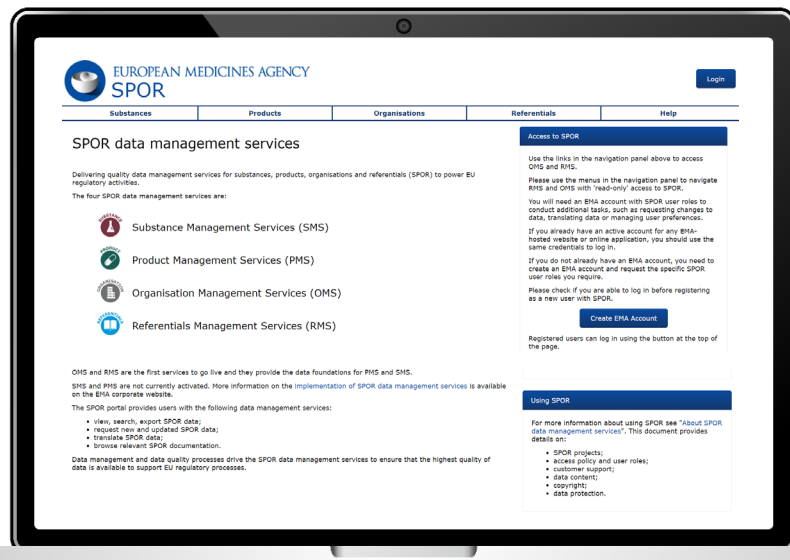
...



ePI CONCEPTUAL MODEL

ePI use of SPOR

Substance **P**roduct **O**rganisation **R**eferential master data ([link](#))



- **Organisation Management Service** ([OMS](#))
 - Author (OMS ID)
- **Product Management Service** ([PMS](#))
 - Product (MedicinalProductDefinition ID)
- **Referentials Management Service** ([RMS](#))
 - Domain ([100000000004](#))
 - Document type ([100000155531](#))
 - Language code ([100000072057](#))

ePI conceptual model

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How to use ePI's API & demo

Introduction to FHIR REST
API, in the context of ePI



Annex

- ePI logical data model
- ePI FHIR resources and key attributes





ePI's API & DEMO

ePI FHIR REST API

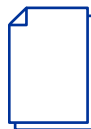
- Style: HTTP VERB [Service URL]/[Resource type]/{?[parameter expression]}
- GET <ePI server>/List/[id] or GET <ePI server>/List?identifier=gona-f
- Available ePI operations: read and search.
- Content type: XML, JSON or RDF (set Accept header or parameter _format)
 - Application/fhir+xml or application/fhir+json
- Authentication: set Ocp-Apim-Subscription-Key header using your subscription key
- Timestamp in ISO8601-UTC (lastUpdated attribute 2021-06-26T01:07:26.194+00:00)
- Rate limit in place – submit a request, *min*, every 3"

Useful links & demo



Services:

- ePI API PoC: sign-up, register and read about ePI API – click [here](#)
- ePI WebUI PoC –click [here](#)
- RMS/OMS: sign-up, search for lists, terms and organisations – click [here](#)
- *PMS API: sign-up, register and read about ePI API <only by EMA> - click [here](#)¹*



Documentation:

- ePI API documentation: click [here](#)
- FHIR Overview: click [here](#)
- FHIR REST API guide: click [here](#)
- Information about SPOR: click [here](#)
- RMS & OMS API specification: click [here](#)
- *SMS & PMS API specification: click [here](#)¹*
- *EMA ePI API repo: click [here](#)¹*



Any questions?

Further information

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Telephone +31 (0)88 781 6000

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ePI conceptual model



ePI's API & demo



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ePI logical data model



ANNEX

ePI logical data model

ePI

- id: str (FHIR)
- versionId: int (FHIR)
- lastUpdated: str (FHIR)
- status: str (FHIR)
- domain: str (RMS)
- medicineName: str
- marketingAuthorisationHolder: str (OMS)
- authorisationNumbers: array[str]

1

*

Document

- id: str (FHIR)
- versionId: int (FHIR)
- lastUpdated: str (FHIR)
- status: str (FHIR)
- title: str (FHIR)
- author: omsID (OMS)
- languageCode: str (ISO 639-1)
- documentType: str (RMS)
- binaries: array[str] (Base64)
- pmsProducts: array[pmsID] (PMS)
- sections: array[section] (FHIR)

ANNEX

FHIR List

ePI

- id: str (FHIR)
- versionId: int (FHIR)
- lastUpdated: str (FHIR)
- status: str (FHIR)
- domain: str (RMS)
- medicineName: str
- marketingAuthorisationHolder: str (OMS)
- authorisationNumbers: array[str]

1

*

Document Reference

- languageCode: str (ISO 639-1)
- documentType: str (RMS)
- documentReferences: array[str] (FHIR)

1

FHIR Bundle/Composition

Document

- id: str (FHIR)
- versionId: int (FHIR)
- lastUpdated: str (FHIR)
- status: str (FHIR)
- title: str (FHIR)
- author: omsID (OMS)
- languageCode: str (ISO 639-1)
- documentType: str (RMS)
- binaries: array[str] (Base64)
- pmsProducts: array[pmsID] (PMS)
- sections: array[section] (FHIR)

1