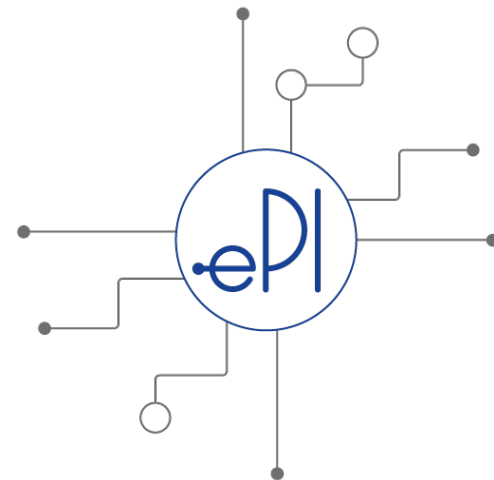


FHIR and the EU common standard for ePI

Information Workshop on electronic Product Information (ePI)



ePI

Set-up project: deliverables

Deliverable

#1

Create an **EU common standard** based on FHIR for ePI in the EU to support harmonised ePI across the EU and collaboration across the network

Deliverable

#2

Provide a **proof-of-concept prototype** using the common standard. The prototype will be used for a design and technical feasibility study to generate some example FHIR-based documents associated with products in SPOR to publish on a website. This is not a business-ready solution

Deliverable

#3

Provide a realistic medium-term **vision and road map** to achieve the benefits for stakeholders, HMA, EC, EMA MB, as outlined in the [Key principles for ePI on the EU](#)

Data, standards, interoperability and APIs

- The need to increase the use of data to support decisions is very prominent inside and outside of the EMA

Fun fact: the word “data” is present 215 times in the [EMA's Regulatory Science Strategy to 2025](#)

- Data is an asset that can only be leveraged if it is “understood” (syntactically and semantically)
- Data is typically managed by multiple information systems that need to collaborate (interoperability)
- Data format and exchange standards are the cornerstone for system inter-operability
- The EMA and the EMRN are committed to interoperable solutions and APIs based on standards
- SPOR (SMS and PMS) already are based on FHIR APIs

API – what it is and what it is not

An API is

- Application Programming Interface
- Meant to be used for machine-to-machine communication
- *"It expresses a software component in terms of its **operations, inputs, outputs, and underlying types**" (source [Wikipedia](#))*
- A "contract" published by a system describing the means and the rules to communicate with it

An API is not

- A database or a server
- A software component that you install on a computer
- A process that automates human activities

What is FHIR?



- [FHIR](#) is a recent standard from HL7 that makes it easy and quick to build REST(*) based APIs for healthcare applications. FHIR solutions are built from a set of modular components called "Resources"
- A general introduction to FHIR can be found here:
<http://hl7.org/fhir/summary.html>

FHIR in one slide

Fast
Healthcare
Interoperability
Resources



a set of XML (and/or JSON) health data resources, plus a REST API for accessing them

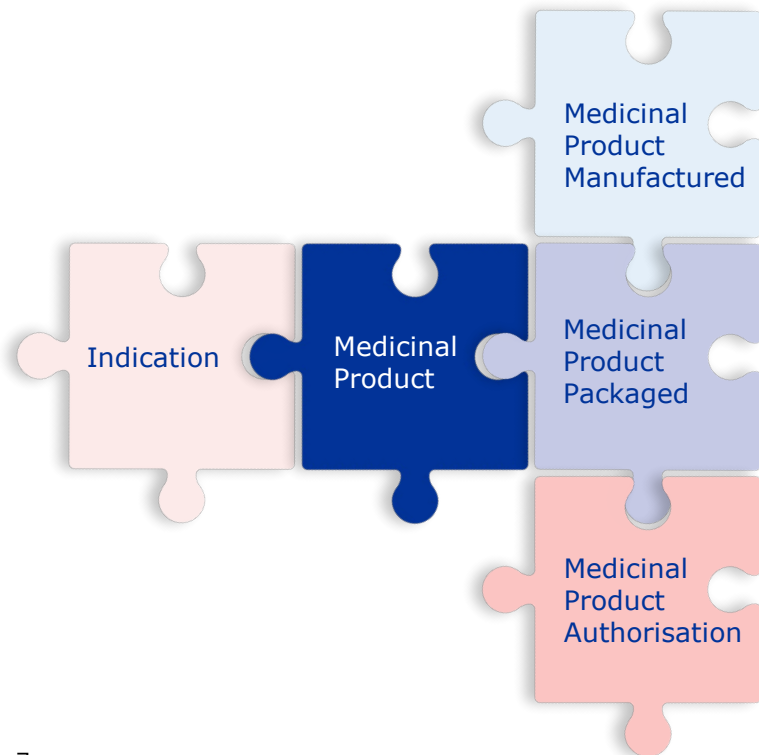
- New free and open healthcare data API
- Builds on simplicity of HL7 V2
- With modern (web) standards
 - XML, JSON, HTTP, REST, UML
 - Familiar to new generation of developers
- Easy to implement the basics
- Getting very rapid take up

Advantages of FHIR

- Focus on implementation – fast and easy to implement
(multiple developers have had simple interfaces working in a single day)
- Specification is free for use with no restrictions
- Multiple (free) implementation libraries – many examples available to kick-start development
- Interoperability "out of the box" – base resources can be used as is, but can also be adapted for local requirements
- Strong foundation in Web standards – XML, JSON, HTTP, OAuth, etc.
- Support for RESTful architectures, exchange of information using messages or documents, and service based architectures
- Concise and easily understood specifications
- A human-readable serialization format for ease of use by developers
- Getting very successful and widely adopted



FHIR Resources



Resources are:

- Small, logically discrete units of exchanged data
- Defined behaviour and meaning
- Known identity/ location
- Smallest unit of transaction
- Connected by "references"

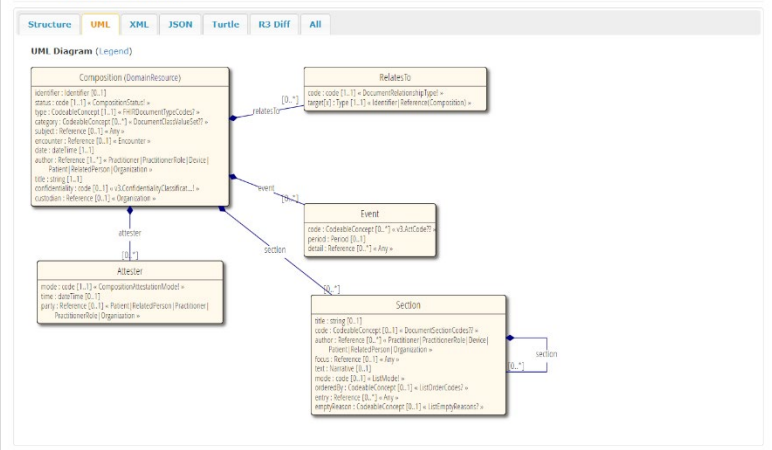
FHIR Resources

- All FHIR resources are publicly described [here](#) and can be used by anyone
- There is a wealth of tools that help to build applications based on FHIR
- Changes to resources are governed by the FHIR community (HL7+members) and is strongly pragmatic (based on general use)

11.11.2 Resource Content

Structure	UML	XML	JSON	Turtle	R3 Diff	All
Structure						
Name	Flags	Card.	Type	Description & Constraints		
MedicinalProduct	Σ TU		DomainResource	Detailed definition of a medicinal product, typically for uses other than direct patient care (e.g. regulatory use) Elements defined in Ancestors: id, meta, implicitRules, language, text, contained, extension, modifierExtension Business identifier for this product. Could be an MPID Regulatory type, e.g. Investigational or Authorized If this medicine applies to human or veterinary uses The dose form for a single part product, or combined form of a multiple part product The legal status of supply of the medicinal product as classified by the regulator		
identifier	Σ	0..*	Identifier			
type	Σ	0..1	CodeableConcept			
domain	Σ	0..1	Coding			
combinedPharmaceuticalDoseForm	Σ	0..1	CodeableConcept			
legalStatusOfSupply	Σ	0..1	CodeableConcept			

2.41.4 Resource Content

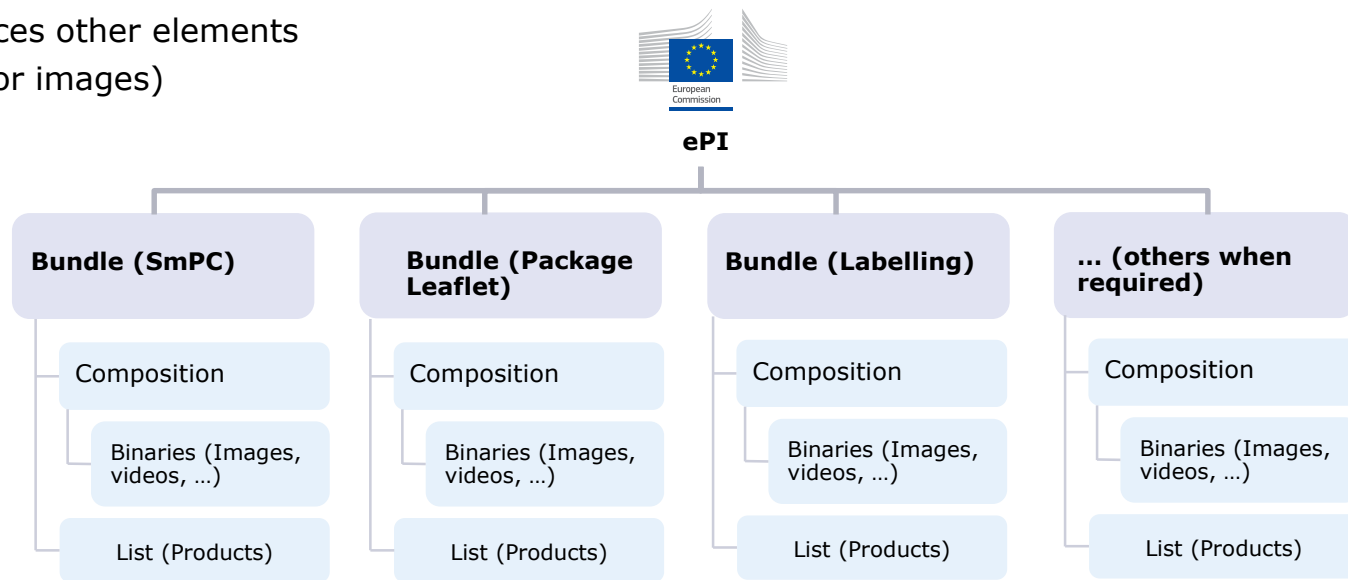


Feasibility analysis of FHIR for ePI conclusion

- FHIR 'Composition' resource fit for purpose for PI documents
- Composition references other elements (Medicinal Products or images)



Use a 'Bundle'

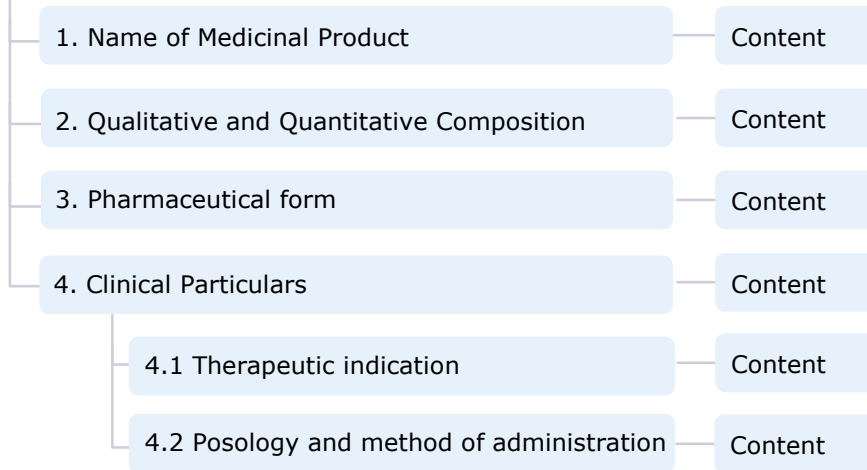


QRD representation in FHIR

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

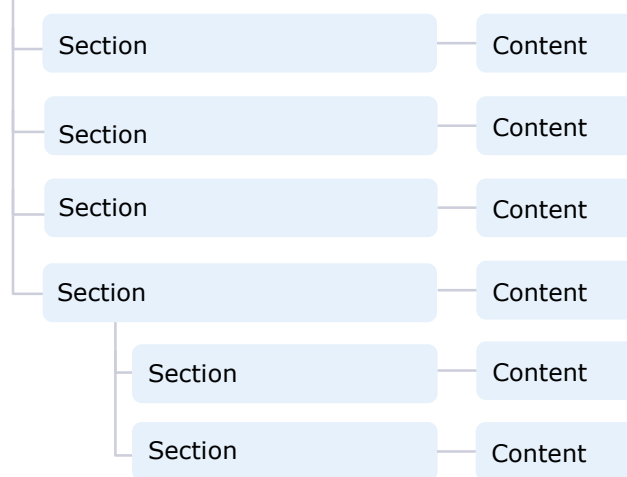
PI Document (SmPC)

SmPC



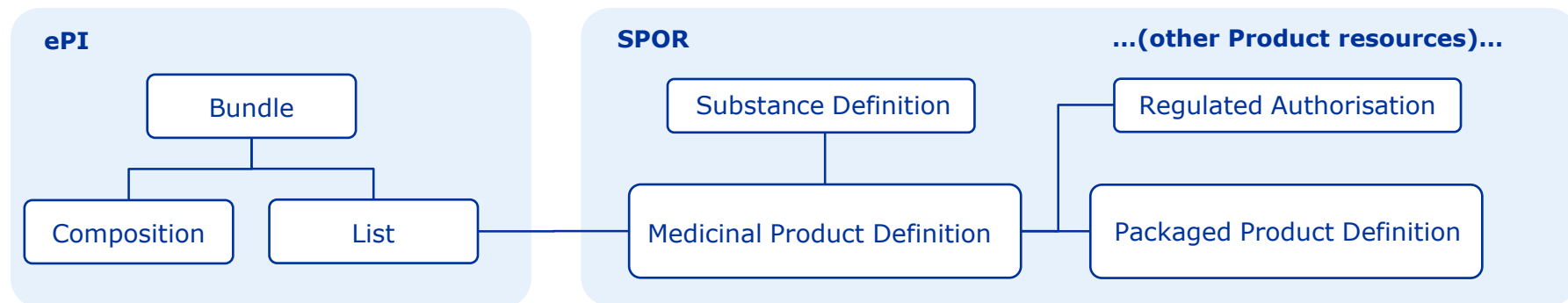
ePI FHIR Bundle (SmPC)

Composition



FHIR in ePI and SPOR master data

- SPOR uses FHIR to represent IDMP-compatible Products and Substances
- ePI uses FHIR to represent unstructured documents in a more structured way
- ePI and SPOR resources do not currently overlap, they interconnect
- Both systems share data interoperability principles, standard, conventions and best practices
- The same FHIR tools and expertise can be leveraged by both systems



Public consultation on EU common standard for ePI

- The consultation is being carried out on the following documents, published on GitHub:
 - 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 a linked survey





Any questions?

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