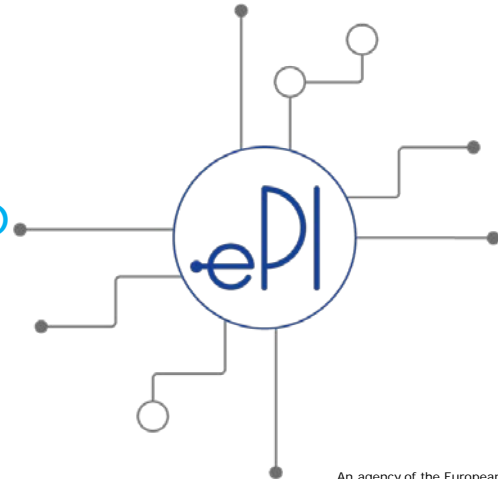


Common electronic standard: potential features and use cases

EMA/HMA/EC workshop on electronic Product Information (ePI)



Emerging key principle

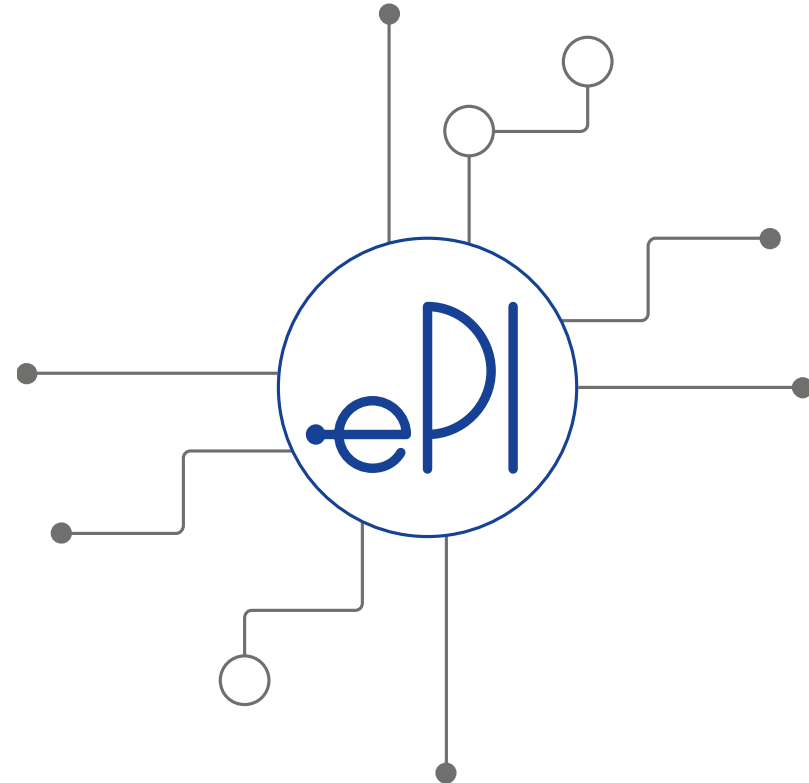
“ePI in the EU/EEA for all medicines will be created using a common electronic standard”

Definition

Technologies

Features

Use Cases



Definition

Draft definition of common standard



The technical features (including mark-up language, controlled vocabularies and interoperability specifications) agreed by regulators and stakeholders. The standard will be used to generate ePI that fulfils the agreed key principles.

Technologies



Languages are used to 'mark-up' or annotate the text of the ePI

Examples: XML, JSON

Purpose? Allow content to go on web pages



Standardised **vocabularies** describe indications, formulations, adverse effects, and other terms

Examples: ISO IDMP/SPOR, MedDRA, SNOMED CT

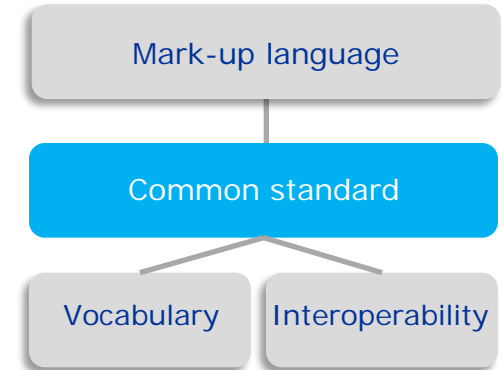
Purpose? Enable searches across PIs and other systems



Internationally recognised **interoperability specifications** allow exchange of information between electronic systems

Examples: FHIR (HL7 standard)

Purpose? Allow ePI to 'talk' to other health systems



Features

Data



Available as **open data** that can be reused in other tools



Use **SPOR (ISO IDMP) terminologies** instead of free text where appropriate



Possible use of ePI throughout **assessment process**



Interoperable with **e-health systems** (prescribing, dispensing, e-health records, cross-border healthcare, CDSS)



Can be **accessed from the package**



Provide **batch-specific** information



Versioning: access to history of PI updates



Ensure data **security** and **privacy**

Features

User experience of applications using ePI



Enable integration of **multimedia** publishing



Capable of delivering **accessible formats**



Allow **layering** and links to relevant information



Multilingual by design



User-friendly **navigation & search**, functionality to save **preferences**



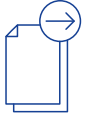
Functionality for **setting up alerts**

Features

Potential future add-on functionalities



Additional efficiencies in the regulatory processes e.g. readability testing



Link to dosing app for tailored dosage regimen, dosing alerts



Support reporting of adverse effects and real-world data collection

Use cases

Patient



List of her medicines
ePI in phone app

Does not remember how to
take asthma medicine



Goes to 'How to take
your medicine' to
downloadable video



Receives alert when ePI
updated e.g. new
safety information

Links to other material



- Educational material
- Lay summaries
- More technical material

Use cases

Healthcare professional



Checks renewal of prescription for chronic condition, new side effect in prescribing system



Approves renewal with:

- message in the personal health record of patient
- contact with patient



- Pregnancy planning
- Lactose intolerance
- Hay fever OTC without drowsiness

Targeted ePI search

Treatment decision

Use cases

Regulator and MAH



ePI allows cascading changes to PI following a variation to the MA

- MAH change address
- Originator submits variation to 4.4 "*Special warnings and precautions for use*"
- Art.31 referral introduces "*Undesirable effect*" for active substance

- MAH informs regulator and changes ePI data once change is implemented/flagged for updating in all affected PI annexes



Harmonised,
up-to-date PI
available to
patient and
HCPs

Towards a common standard



Compiling requirements



Identifying and assessing candidate standards



Documenting standard in open catalogues and guides



Towards implementation

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