EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

HMA
Heads of Medicines Agencies

European Commission

ePI: Getting the focus right

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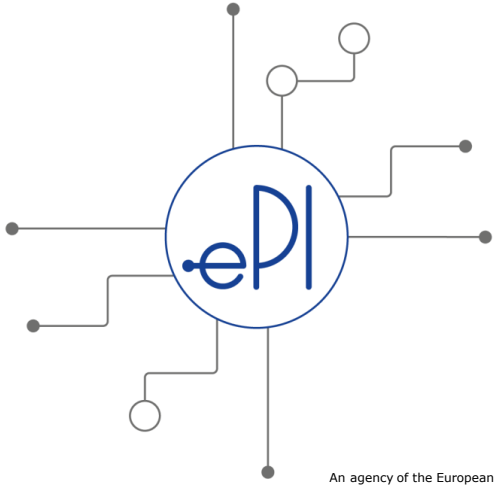
Medicines Evaluation Board (MEB)



CBG MEB

MEDICINES EVALUATION BOARD

Good medicines used better.

Home

- Medicines Information Bank
- Veterinary Medicines Information Bank

Marketing authorisation medicines for human use

Procedures, dossier requirements, pharmacovigilance, policy

Veterinary Medicinal Products Unit

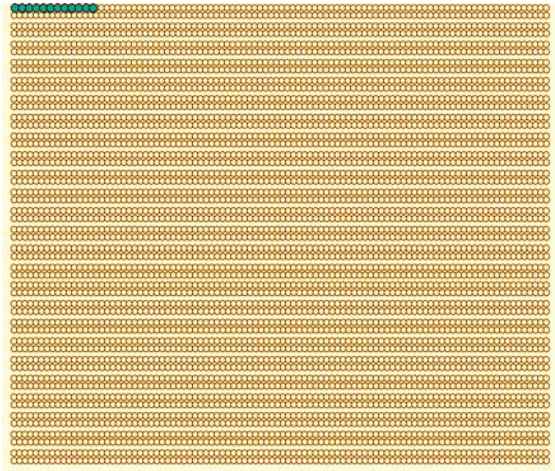
Marketing authorisation, reporting adverse events, production, distribution

About MEB

Objectives, decision-making, cooperation, vacancies, contact

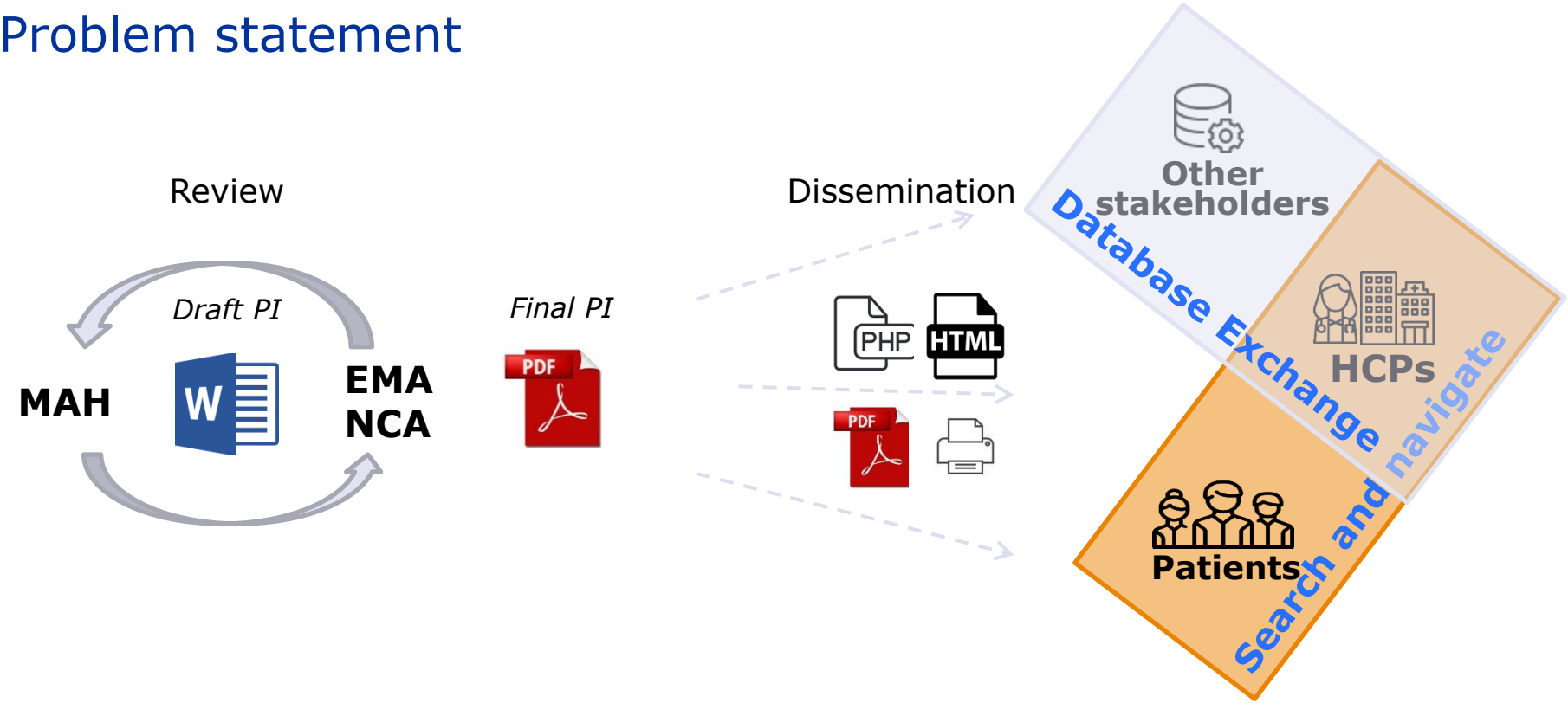
Patients in the driver's seat

Of the 5,000 hours that a patient is awake per year, only a fraction is spent under supervision of a HCP



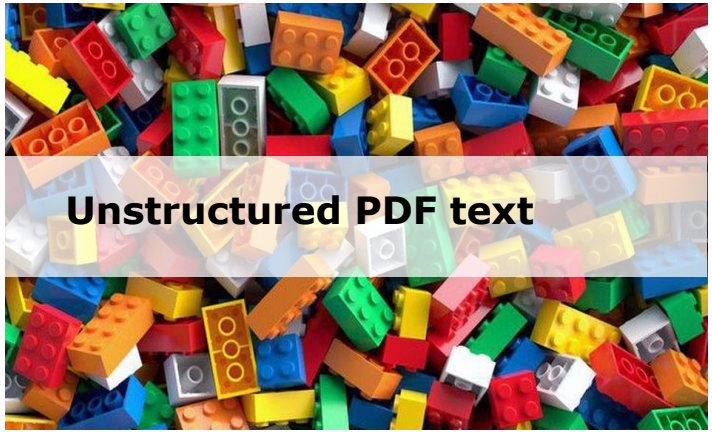
Reliable information on medicines is not easy to find on the internet

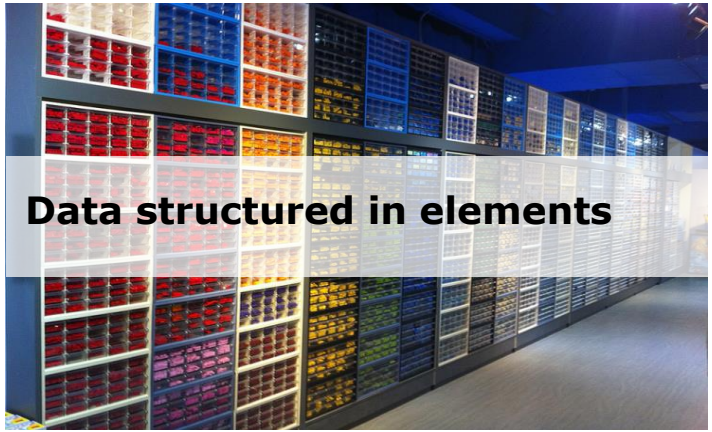
Problem statement



What do we need?

Harmonised and structured PI enabling smart knowledge modelling, that facilitates building and updating regulation into SmPC, PL





Subsequently all kinds of applications on all kinds of devices and channels can be derived from the same source

The right focus

Review

Draft PI

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eQRD

MAH

EMA

NCA

ePI

Dynamic dataset

Dissemination

Other stakeholders

Database Exchange

HCPs

navigate

Search and

Patients

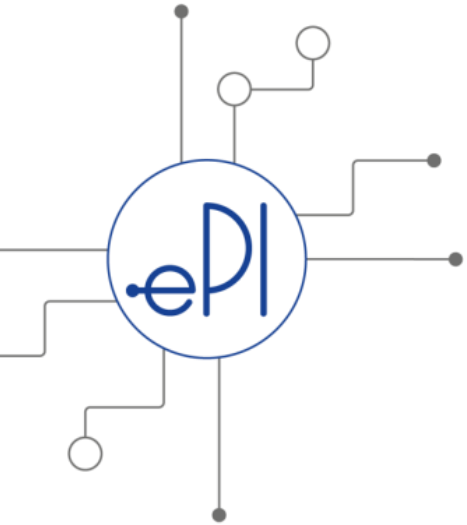
Transitional period

How to build a 21st century PI model?

- Create a common EU electronic standard (utilising eQRD template, etc.) (Key Principle #2)
- Start the implementation by a pioneer group of Member States, who encourage other Members States and stakeholders to join (under Key Principle #9)
- Establish a roadmap for the transitional period towards the full implementation of a harmonised approach to ePI across the EU (under Key Principle #9)
- Commitment by all stakeholders, coordinated by EMA, HMA, and EC

Thank you for your attention

Any questions?



Further information

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See websites for contact details
European Medicines Agency www.ema.europa.eu
Heads of Medicines Agencies www.hma.eu
European Commission www.ec.europa.eu

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