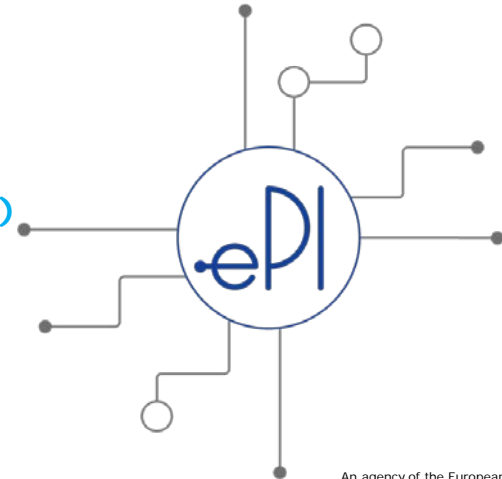
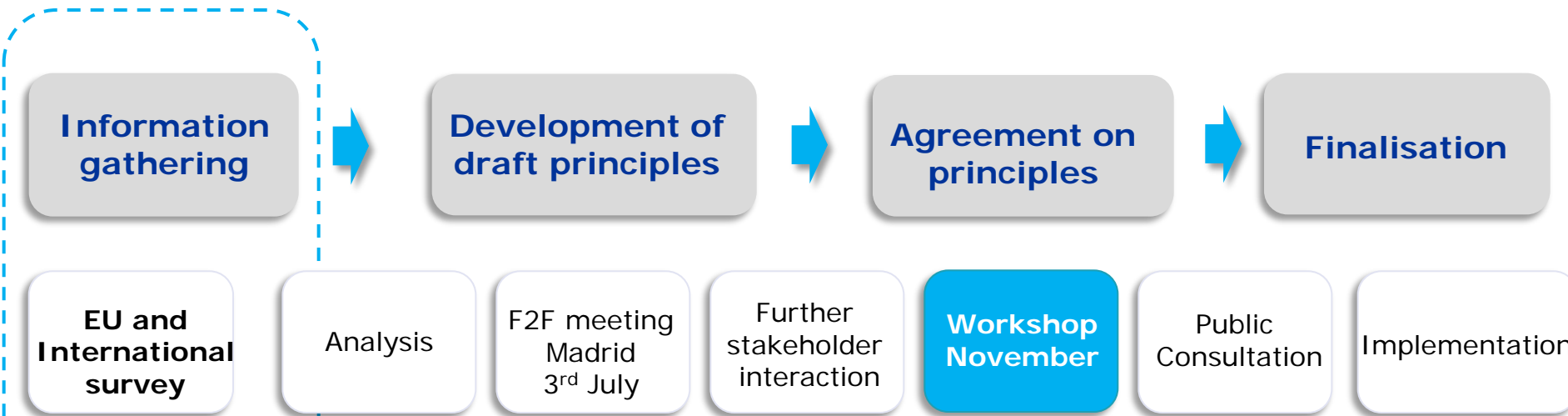


## Overview of initiatives from the EMA-HMA mapping

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



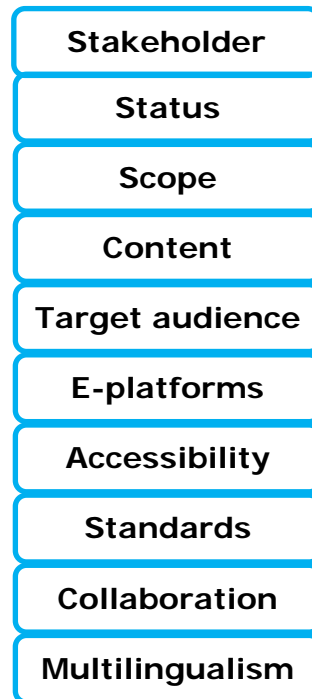
# Work methodology



To map ongoing/planned EU and international initiatives on electronic PI

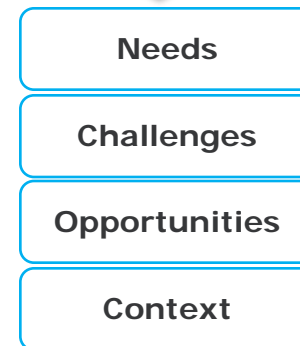
# Mapping– methodology

- Mapping EU ePI initiatives by survey
- Targeted dissemination to EMA's stakeholders and partners



## For each contribution:

- Categorise
- Summarise by stakeholder group
- Qualitative analysis:



## Overview of EU initiatives (I)

81 responses – including 19 NCAs

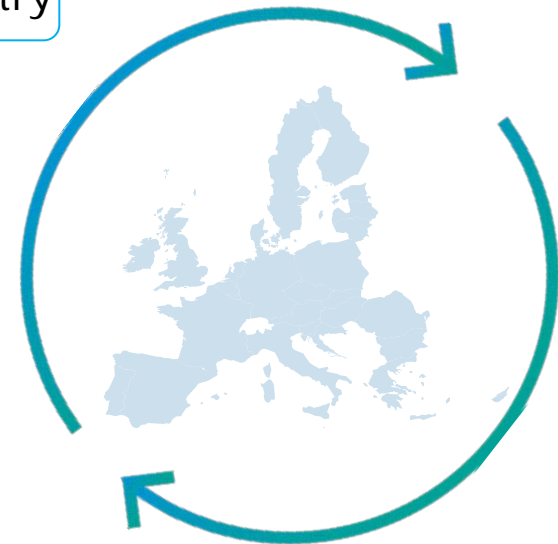
**38** projects underway in the EU, mainly from NCAs or industry

→ Projects at different stages of development, **14 out of 38** are **well established**

→ **NCAs:**

- Spain (ePI available)
- **7** NCAs with ongoing projects

→ Target audiences for most projects (**23**) are *both* **patients** and **HCPs**



## Overview of EU initiatives (II)

- E-platforms include **web (32), video (5), mobile (12), QR codes (5)**
- **14** initiatives mention **accessibility** :
  - e.g. **audible formats** to support **visual impairment**
  - e.g. **videos** to support **low health literacy**
- Several contributions from **industry**  
(including from a cross-industry Task Force)
- **2** collaborative **pilot** studies
- In several countries there are **third-parties** providing ePI
- Where mentioned, **XML** is the electronic standard mostly used



# Overview of international initiatives

Japan + majority of countries



PDF



USA



Labeling is available electronically in US

FDA implemented the Structured Product Labeling (SPL) initiative in 2005



Canada



Plan to transition to e-formats

Switzerland



Electronic PI in 3 languages: FR, DE, IT



Bill and Melinda Gates foundation



Potential project to explore the use of electronic PI and PL instead of paper package leaflets in low income countries

## Key findings

- **Multiple ongoing initiatives** in the EU highlight the **need for coordination**
- The mapping helped identify **representative initiatives**



### Initiatives from National Competent Authorities

- Spain
- Norway
- Sweden



### Initiatives from stakeholders

- Third-party providers
- Industry
- Pilot studies
- Proposed future research

- Trend to move **towards e-formats internationally**
- Need to consider the **possibility to find a global standard** for ePI
- Mapping exercise confirms that this is the **right timing to move to ePI in the EU**

## Acknowledgements

### EMA-HMA mapping team

MJ. Alcaraz (AEMPS)

M. Buch (EMA)

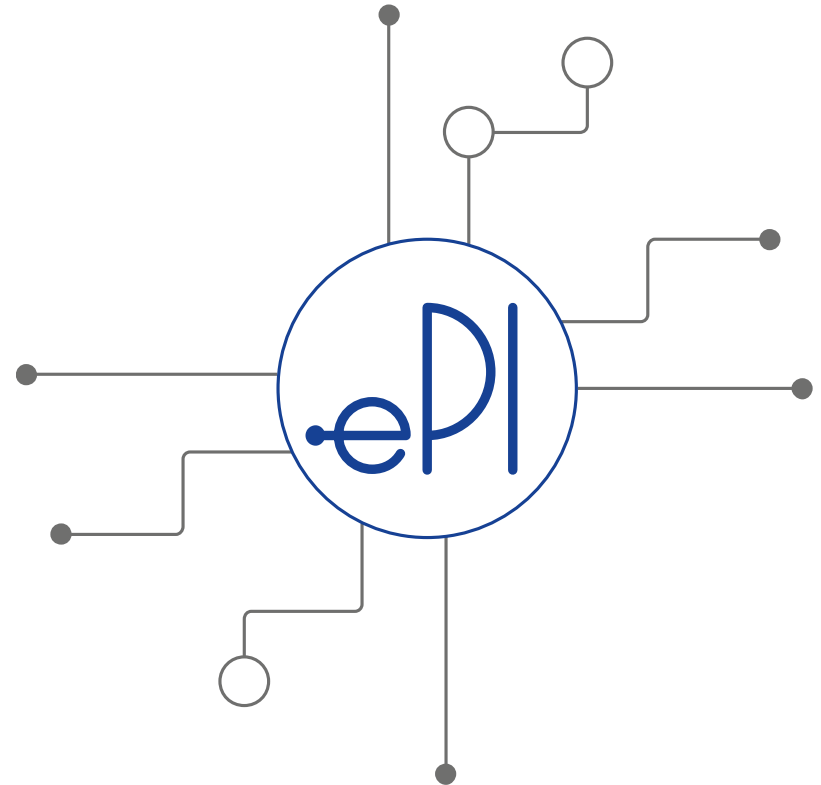
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# Any questions?

## Further information

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