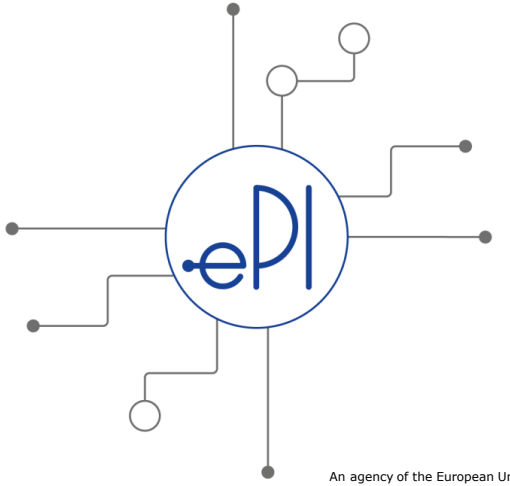
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

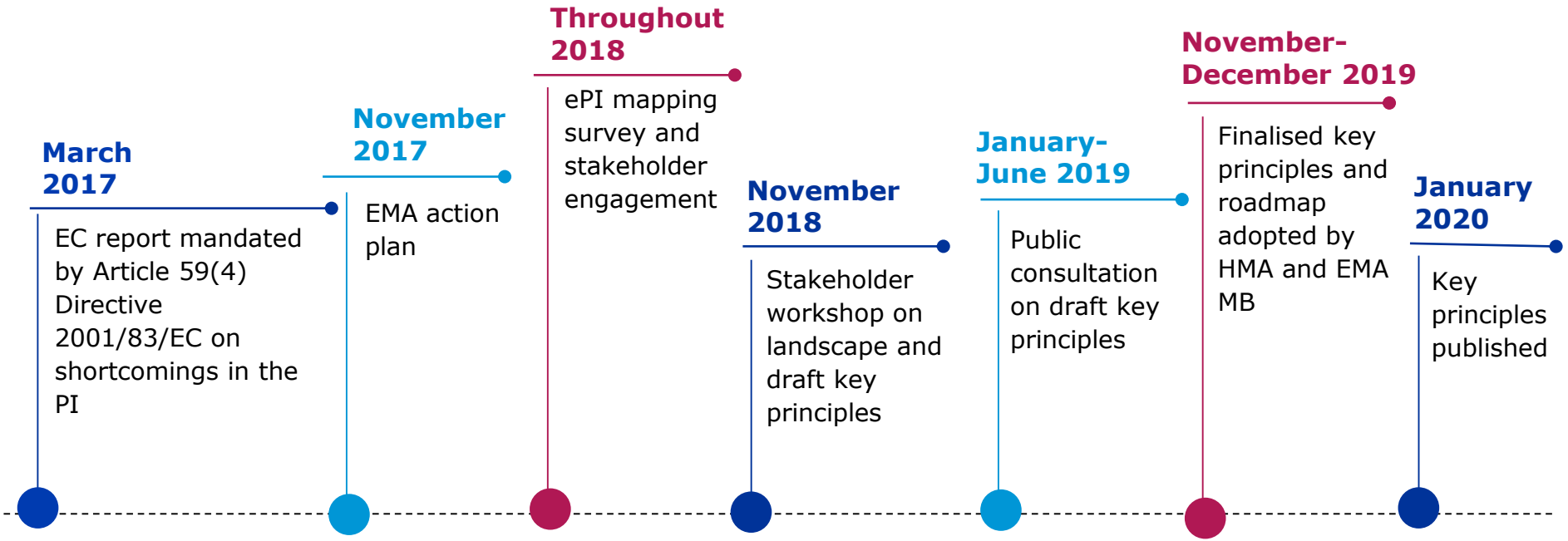
HMA
Heads of Medicines Agencies

European Commission

Electronic Product Information (ePI) for EU medicines



ePI chronology



Definitions

ePI is authorised, statutory product information for medicines (i.e. summary of product characteristics, package leaflet and labelling) in a semi-structured format created using the common EU electronic standard. ePI is **adapted for electronic handling** and allows dissemination via the world wide web, e-platforms and print.

A **common EU electronic standard** for ePI refers to the **technical features** (including mark-up language, controlled vocabularies and interoperability specifications) agreed by regulators and stakeholders. The common standard will be used to generate ePI.

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

ePI key principles

1. ePI and EU common standard definitions
2. Expansion of access to information on medicines
3. Accessibility to users with diverse abilities
4. ***Creation of efficiencies for regulatory systems***
5. Complementarity to paper package leaflet

ePI key principles

6 Open access to regulator-approved information

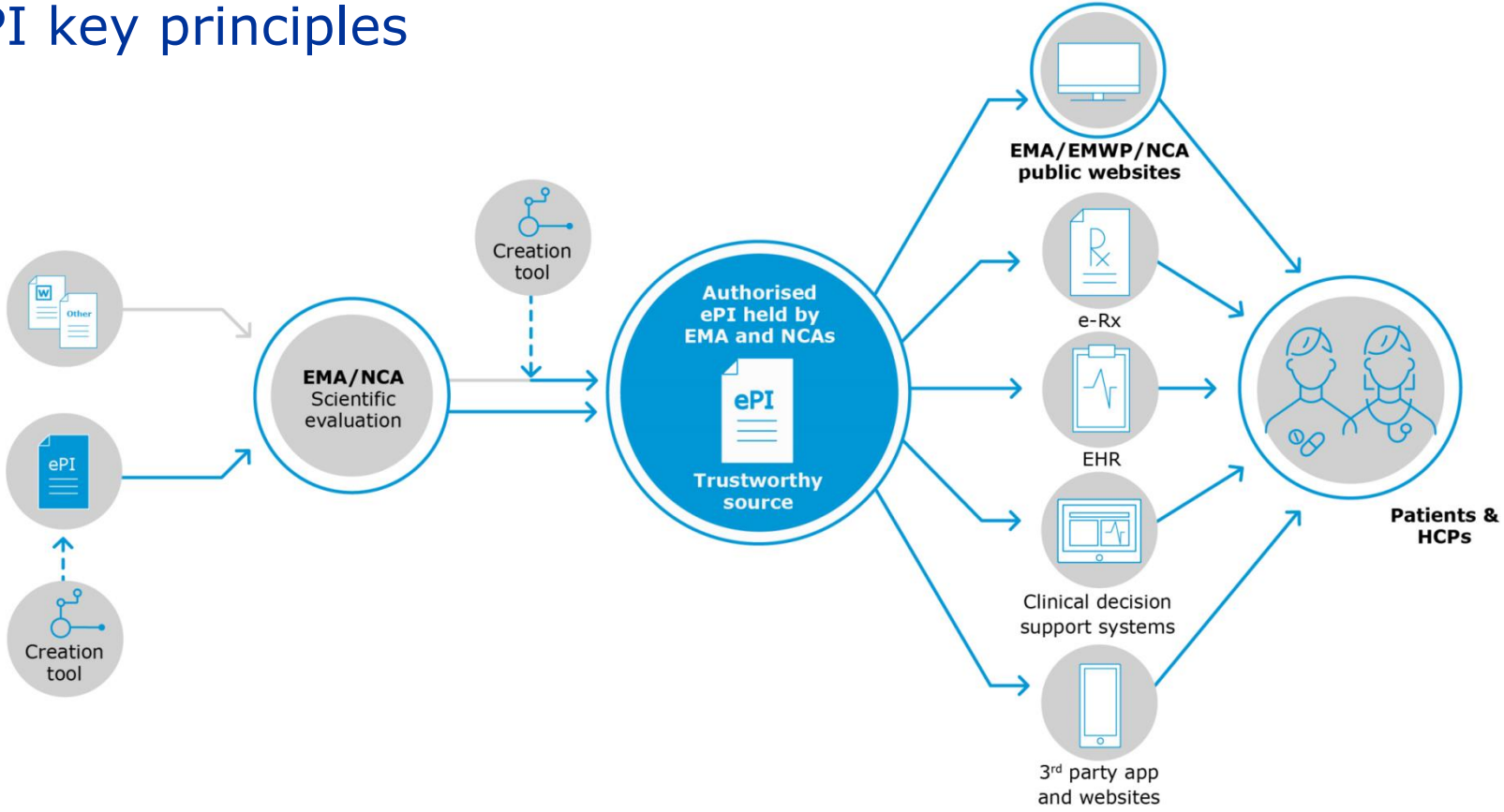
7 Data protection

8 Flexibility in implementation

9 Support for multilingual PI

10 Interoperability with EU and global initiatives

ePI key principles



Public consultation — stakeholder profile

31 January to 31 July

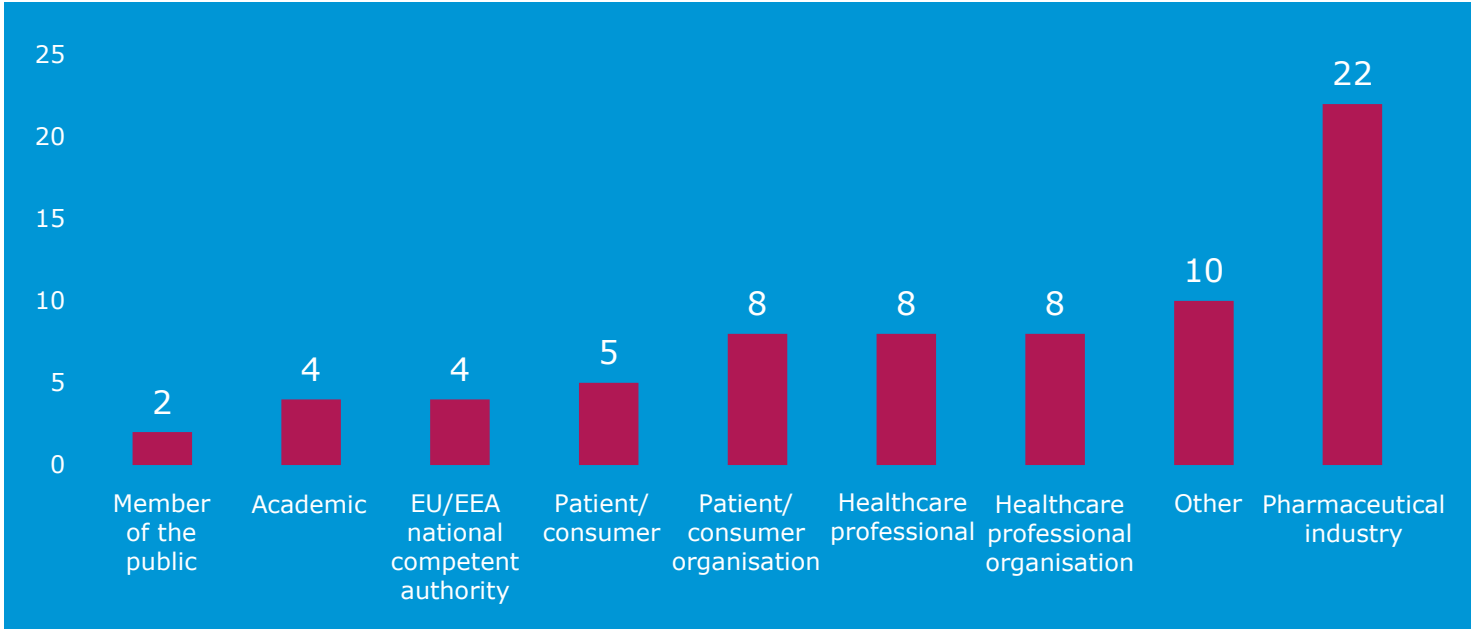
71

submissions

comprising

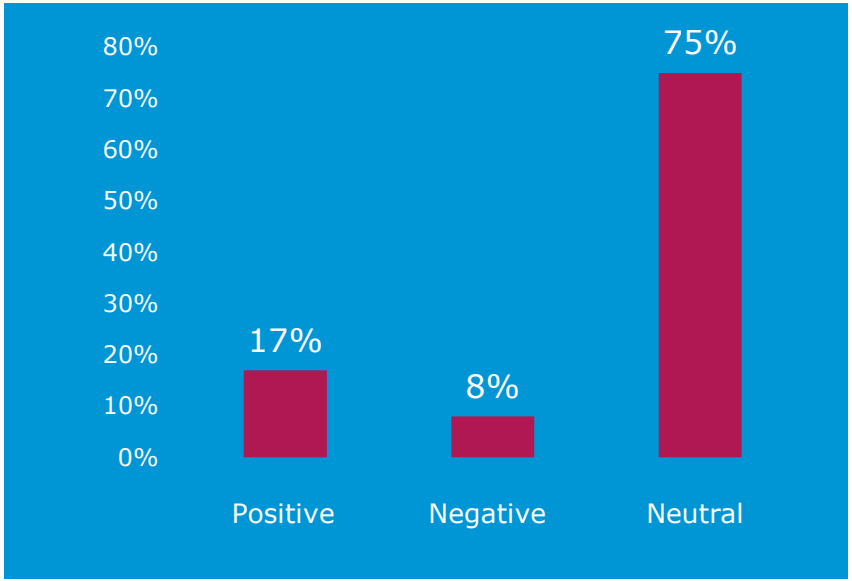
>500

comments



Public consultation — main points & sentiment

- Appetite for widening scope of ePI (e.g. photos of medicines, risk minimisation material, DHPCs)
- Strong wish to also work on PI content
- New key principle on efficiencies in regulatory processes
- Strong views on both sides on principle that ePI complements paper

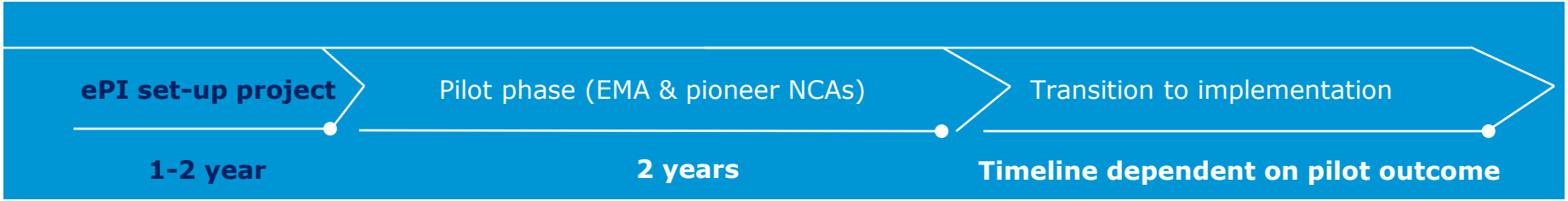


High interest and encouraging support for initiative with just ~8% negative comments

EU Roadmap — implementation on basis of key principles

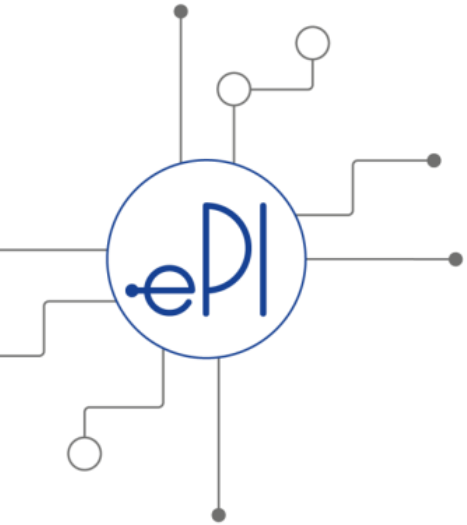
ePI set up project defines common standard and provides tools needed for a pilot phase

Pilot by EMA and some pioneer NCAs tests ePI from end-to-end and assesses impact on current processes



Ongoing consultation with patient and HCP representatives

Any questions?



Further information

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See websites for contact details

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