



# Electronic product information (ePI)

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Aimad Torqui  
Executive Director  
Global Regulatory Policy  
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# Objectives of this presentation

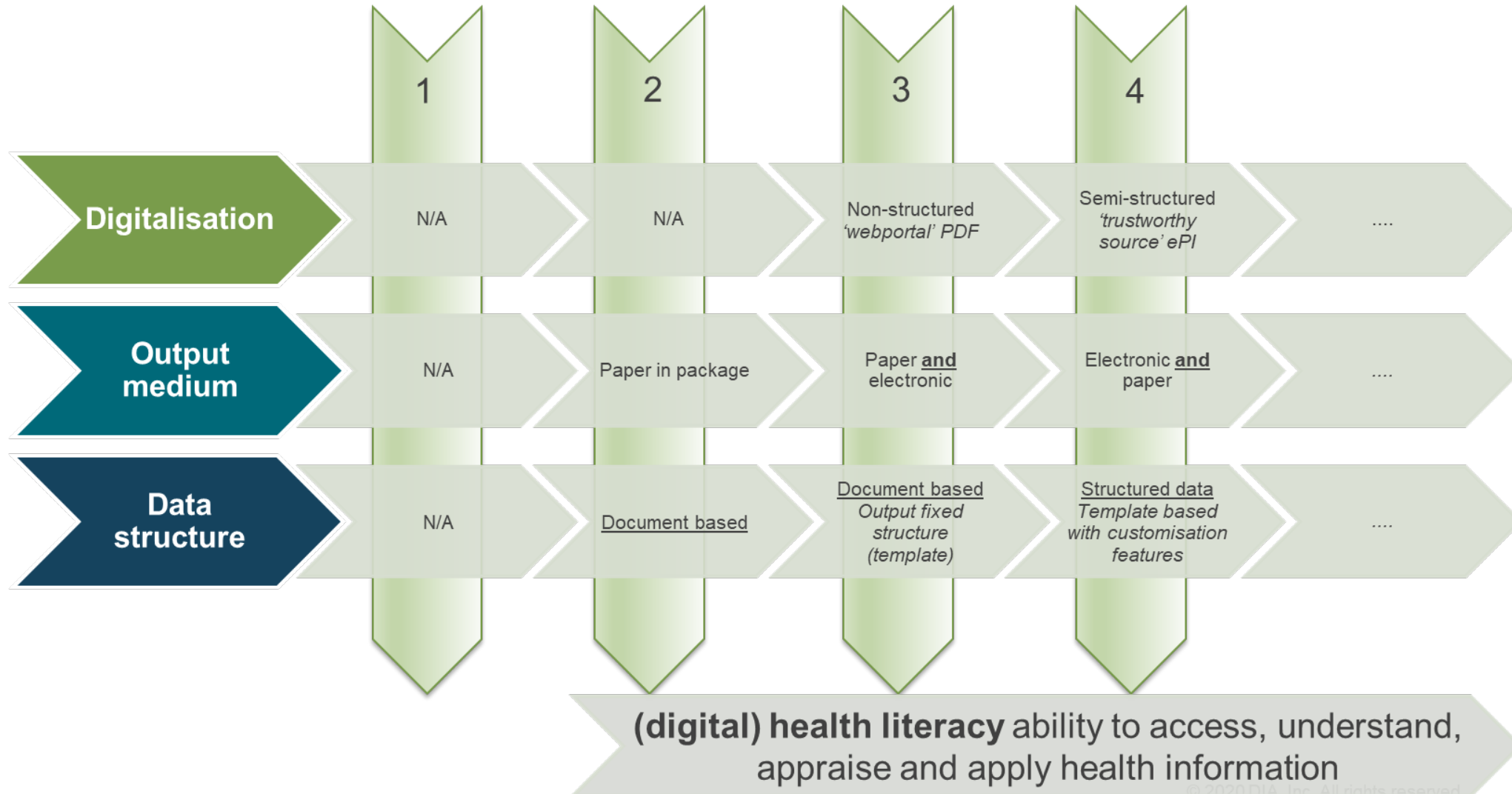
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## Presentation outline ...

- what is electronic product information
- what are we trying to achieve
- what has been done so far
- what are next steps

# What is electronic 'product information'

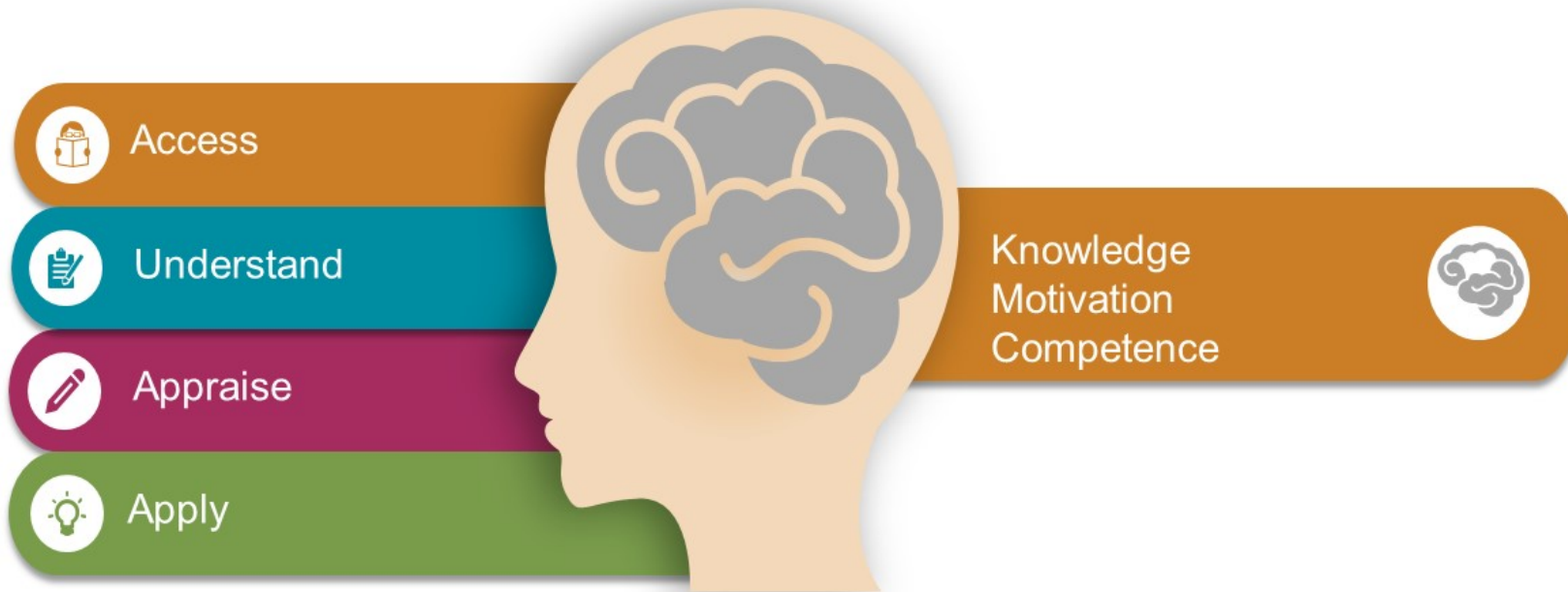
## Different evolutionary steps, driving global vocabulary



# What are we trying to achieve

## Patient centered approach: (digital) health literacy

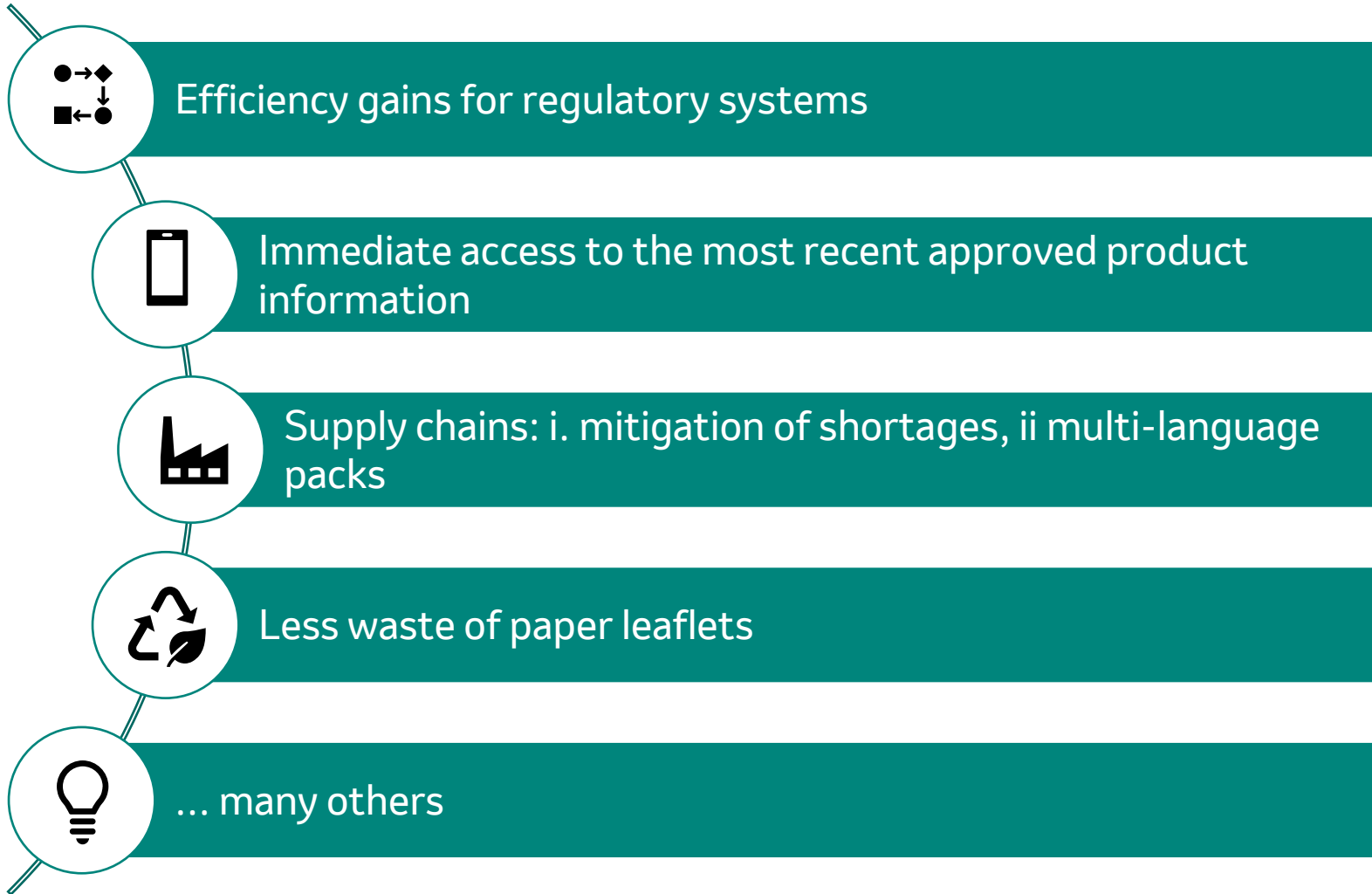
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*'...knowledge, motivation and competences to access, understand, appraise and apply health information in order to make judgments and take decisions in everyday life concerning health care, disease prevention and health promotion to maintain or improve quality of life throughout the course of life'*

# What are we trying to achieve ...and many other benefits

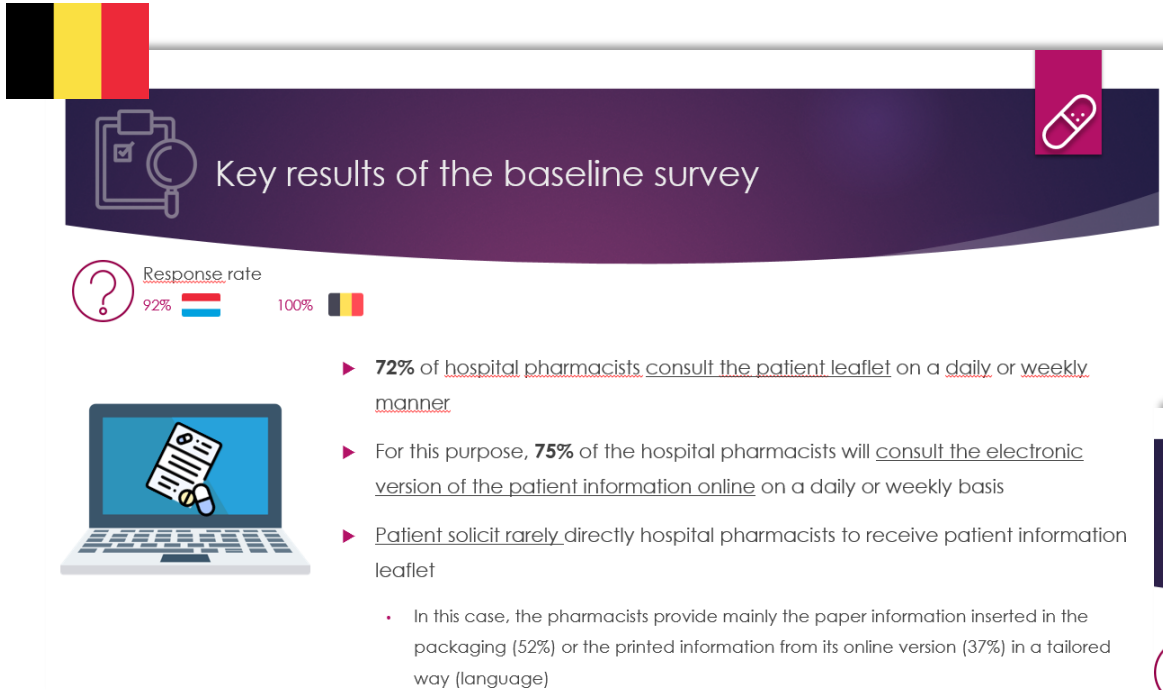
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# What has been done so far

## Innovative pilots are important to guide evolution of ePI



# What has been done so far

## EMA and HMA recognize ePI as a public health priority



### **Electronic product information (ePI) is a public-health priority**

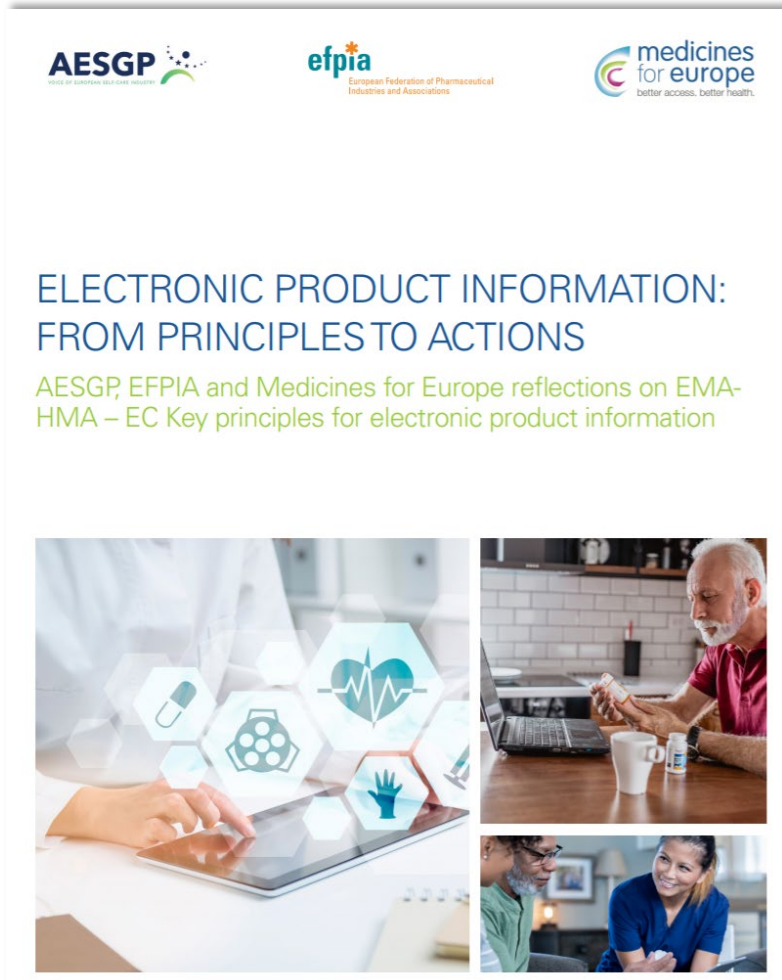
- Provision of the latest information on a medicine's safety, benefits and conditions of use
- Right information is available to the right HCP and patient / consumer at the point of need
- Support informed decision-making

### **New opportunities (long term)**

- Personalization
- Supportive video / audio
- Interactive materials (e.g., dictionaries)
- .....

# What has been done so far

## EU Trade Associations Taskforce support ePI development



### Launch of electronic label pilot(s)

- Agreed roadmap with stakeholders
- Develop common standards
- Architecture of webportal

### Policy and legal aspects

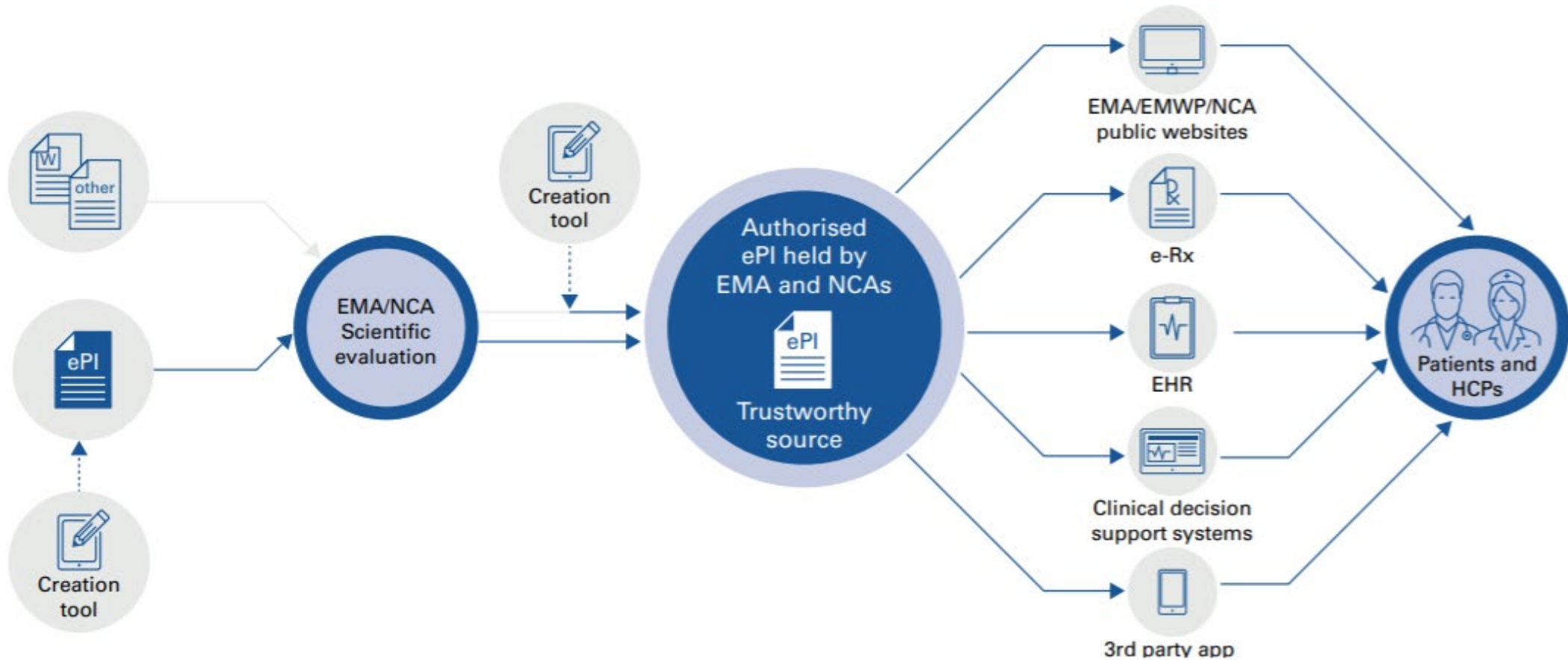
- Mitigate shortages or increase availability in small markets
- Transition to ePI as single source and removal of paper

### Patients and HCP

- Integrate in eHealth strategy
- Educational campaign to raise awareness
- Stakeholders' collaboration on how to improve the content

# What has been done so far

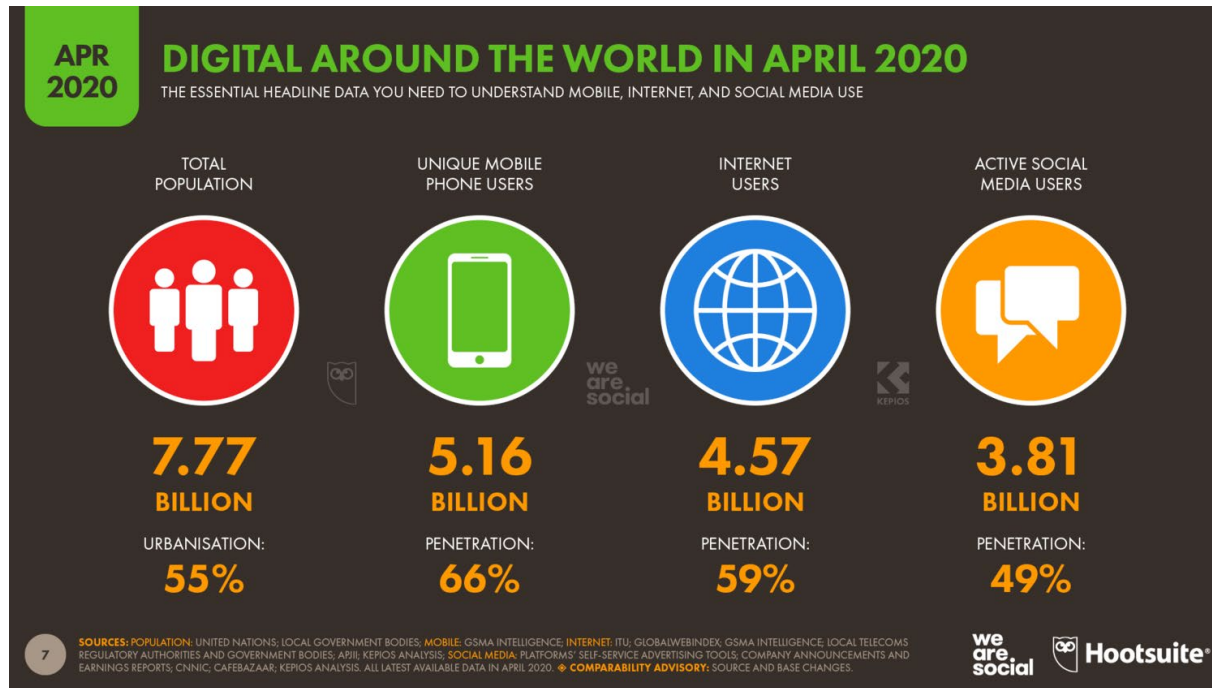
## EU ePI proposed model: regulatory efficiencies and access



(Subject to change following feasibility analysis once ePI project is started)

# What are next steps

## Access to ePI: to guide informed decision-making

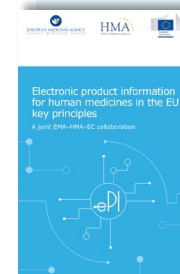


### 2.1. Expanding access to information on medicines as a public health imperative

#### Statement

ePI is a public-health priority because it will expand the dissemination of unbiased, up-to-date, regulator-approved PI for all medicines in the EU. ePI will support, among other functions:

- provision of the latest information on a medicine's safety, benefits and conditions of use;
- better delivery of information so that the right information is available to the right HCP and patient / consumer at the point of need;
- informed decision-making by patients / consumers and HCPs.



*“To achieve this principle, it is technically feasible to make ePI available through various technologies and applications, including mobile scanning technology on the medicine package .....*

*The use of the 2D barcode introduced via the Falsified Medicines Directive may be explored for this purpose”*

# Moving forward ...

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- Ensure (new) regulations are not outdated as technology evolves over time
- Importance of open dialogue with all stakeholders
- Agree and define a joined roadmap with all stakeholders
  - (pilot) projects: to learn, adapt and ensure consistency
  - Global standards and technologies development
  - Accept ePI as the authoritative source of approved information
- Once we can be assured that stakeholders have access and able to use ePI, eliminate the requirement of paper leaflets



# Thank You

Aimad Torqui  
aimad.torqui@merck.com