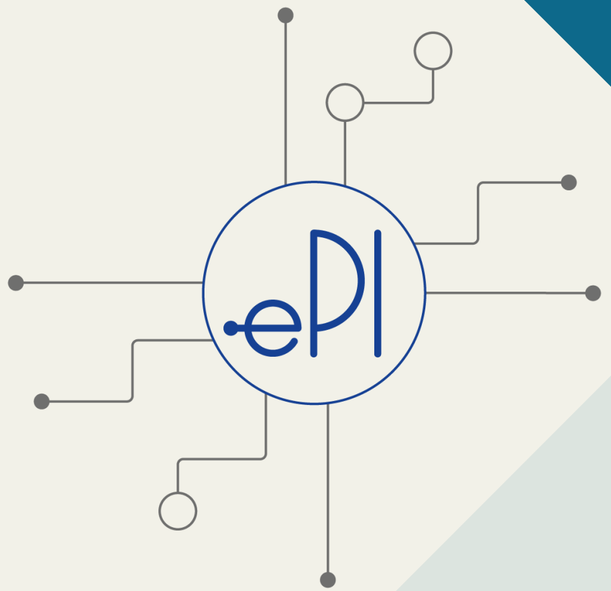
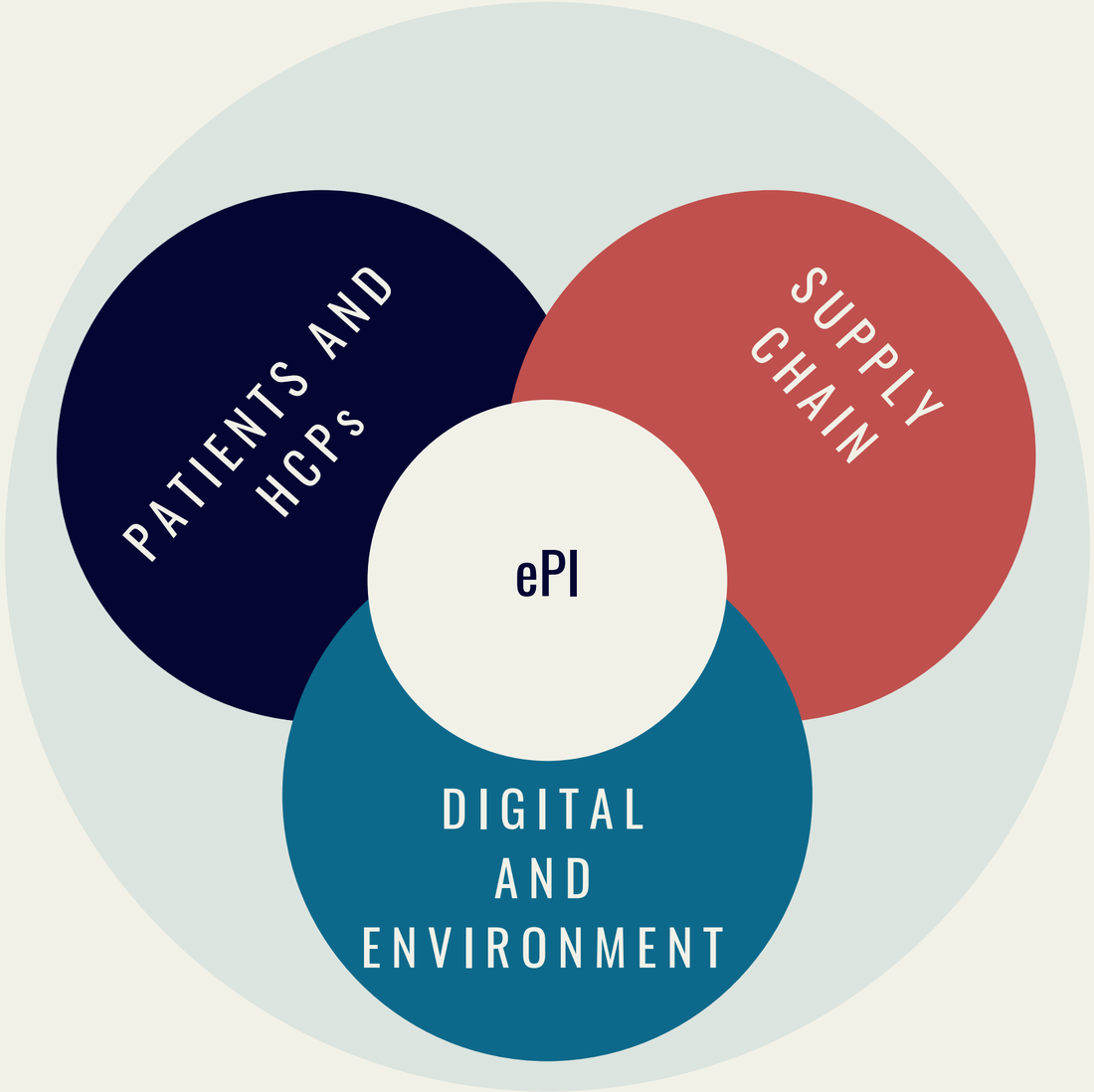
AESGP efpia medicines for europe
better access. better health.

THE BENEFITS OF ELECTRONIC PRODUCT INFORMATION (ePI)





IDENTIFY & CAPTURE

THE BENEFITS

The upcoming pharmaceutical legislation revision must be leveraged to capture the benefits of ePI. Capturing those benefits will require implementation for **both Centrally and Nationally Authorised Products**

PATIENTS AND HEALTHCARE PROFESSIONALS

As the end users of medicinal products, the needs of patients and HCP must be a priority in the development and implementation of ePI

SUPPLY CHAIN

ePI can strengthen the supply chain of medicines by participating in the mitigation and prevention of shortages

DIGITAL AND ENVIRONMENT

Digitalisation of product information delivers directly on EU's digital and green ambition, reduce waste and therefore could decrease the carbon footprint of Pharmaceutical sector

PATIENTS' ACCESS TO INFORMATION

- ePI could provide **immediate** access to the **most recently** regulator-approved product information.
  - This is especially relevant in cases of safety updates, recall,…
- This would require to have ePI integrated to the regulatory dossier

PATIENTS' ACCESS TO INFORMATION

- By providing **tailored information** on end-user needs and facilitating search for information and support advance features (such as videos and voice delivery), ePI will:
  - support better delivery of information to enable informed decision-making, (ex. visually impaired patients)
  - participate in advancing health literacy amongst patients,
  - Enhance safe use of medicinal products, and improve treatment adherence

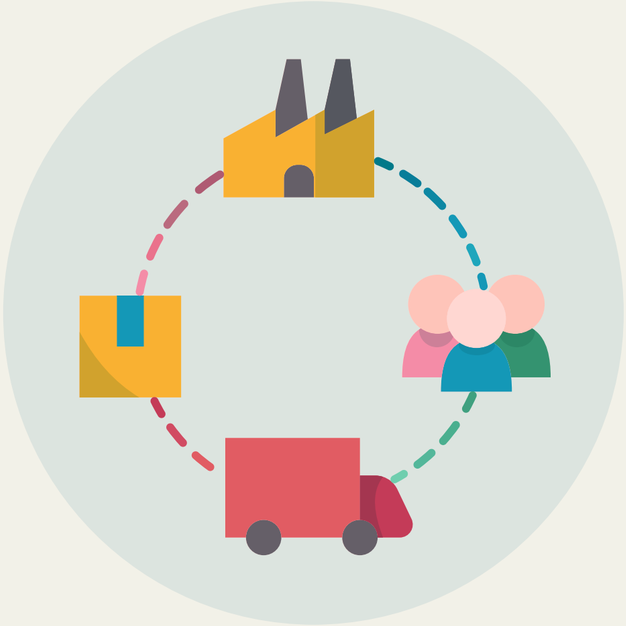
REGULATORY EFFICIENCY

- ePI can bring regulatory efficiencies and operational excellence through a harmonized implementation across Europe to the benefit of regulators and Industry
- ePI must be created within the regulatory dossier and based on automated data filling from systems such as SPOR for structured data to ensure that changes can be made directly into systems and only the relevant section of the PI will need to be updated.

➡ Updates can then reach users in almost real time

SUPPLY CHAIN

- EC Studies on Shortages and on pharmaceutical legislation review clearly recognize the value of ePI in this area
- Increased access and availability of medicines via multilingual packages, notably in smaller markets
- ePI could promote mitigation of medicines shortages by allowing faster reallocation of packages without the need to replace the leaflet and repackaging.



DIGITAL AND GREEN TRANSITION

- According to the Green Deal, the digital transformation is a key enabler for reaching the Green Deal objective of reducing waste
- Digital by default would support clean and circular economy and is an asset to reduce the carbon footprint of the pharmaceutical sector:
  - Outdated leaflet will not have to be removed and replaced, or worse, the batch will not be destroyed
  - Ultimately, removing the paper leaflet will save tons of paper and ink every year.

WHAT IS NEEDED TO GET THERE

- The current legislation must be modernised and future-proofed to respond to digital evolution and evolving patient needs
- SPOR should be ready to maximise the benefits of ePI
- ePI must be developed and timely implemented for all medicines in Europe. None should be left behind. Digital inclusion is a key for the success

BUILDING FOR THE DIGITAL FUTURE

- A step-wise approach informed by the Digital inclusion principle
- In complement to the current EMA ePI Pilot, build on existing learning (BE pilot, COVID19 vaccines, survey from hospital pharmacists, common position paper)
  - ➡ Issue an EU-wide pilot for medicines that are directly administered by healthcare professionals
- Base future steps on patient centricity
  - ➡ Contents improvement
  - ➡ Look at alternative ways to equip patients and end-users with the most updated product information

REFERENCES

- Electronic Product Information: from principles to action – *AESGP, EFPIA, and Medicines for Europe reflections on EMA-HMA-EC Key principles for electronic product information*
- EAHP Survey: the future potential of electronic product information (ePI)