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Electronic product information:
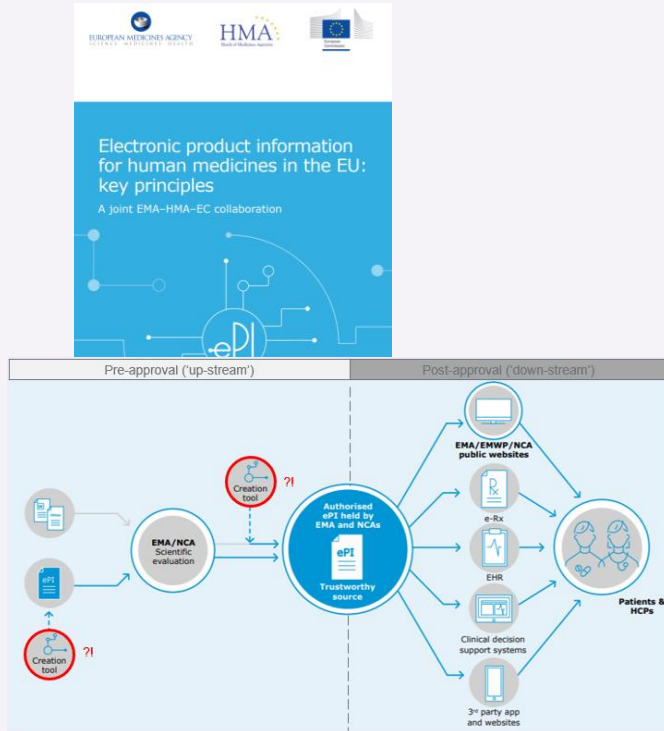
Benefits and challenges

Sabine Faber   5 October 2023

9th Pharma Packaging and Labeling Innovation Forum, Berlin

Electronic product information (ePI)

*published in Jan 2020

Key principles on ePI*

❖ **Definition**

Electronic product information' (ePI):

authorised PI in semi-structured format using a common electronic standard

❖ **Process**

Implementation in stepwise approach
(goal: submission of ePI in structured format)

❖ **Implementation**

within current legislative framework

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The benefits of electronic product information

For Patients & Healthcare Professionals (HCPs)

- User-friendly format providing tailored information (e.g. zoom/search function)

- Most up-to-date PI(L)

- Always available

- Enhance safe use of medicines

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The benefits of electronic product information

For Industry & Health Authorities

- More efficient approval processes

- More efficient and flexible production and packaging processes

- Strengthen supply chain -

  facilitates re-allocation to mitigate shortages

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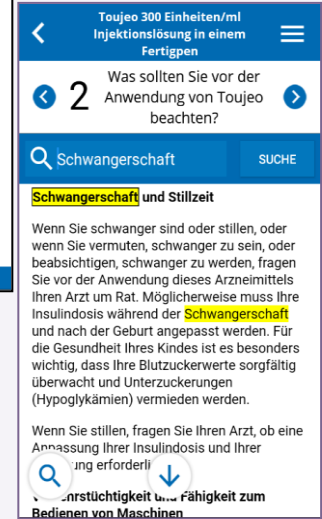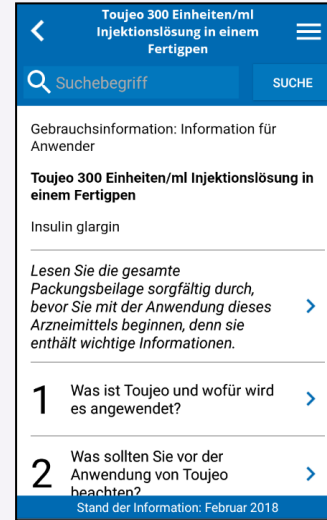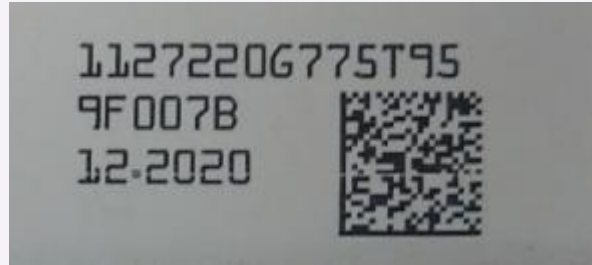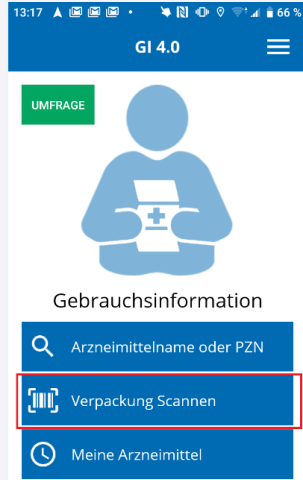# The benefits of electronic product information

For Environment & Sustainability

If ePI replaces the PI(L)

- Reducing waste

- Reducing consumption of paper and ink

- Contribution to carbon foot print

German GI 4.0® tool -Fast & easy access to user-friendly newest PIL

Accessibility by scanning the Datamatrix-Code or barcode on the box

User-friendly, always up-to-date digital (xml based) PIL

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The challenges of electronic product information

What is needed to get there?

Legal framework:

➡ Current review of the EU Pharmaceutical Legislation as opportunity to get paper package leaflets replaced by electronic versions

- Full transition to electronic patient information in a stepwise approach, e.g. starting with HCP-administered products

- Acknowleding different digital literacy of patients/users in the countries by providing interim solutions (e.g. print-out option)

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The challenges of electronic product information

What is needed to get there?

- Development of harmonized IT infrastructure for ePI implementation, like EMA activities, and their timely implementation across (EU) countries

- Accessibility by scanning the code on the package of medicines

Option: Datamatrix-Code ('serialization code')*:

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* requested by Falsified Medicines Directive in Europe or other regulations world-wide

The challenges of electronic product information

What is needed to get there?

Datamatrix-Code (DMC)– WHY?

- Already implemented on boxes for almost all Rx medicines*
- Single code approach ensures clarity to users and avoid risk of scanning errors
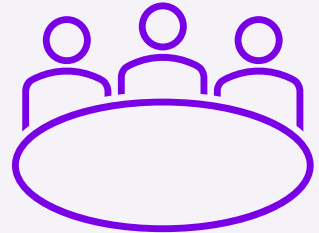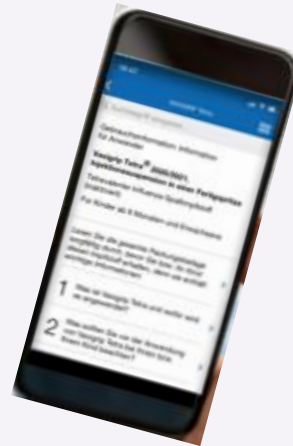- Option to use additionally embedded information (batch, expire date)

➡ Technical solutions for easy access of DMC (e.g. without app) should be developed!

(QR codes available for interim phase)

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The challenges of electronic product Information

What is needed to get there?

CLOSE COLLABORATION AND PARTNERING OF ALL STAKEHOLDERS
INCLUDING INDUSTRY, AUTHORITIES, PATIENTS, HCPS

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In conclusion

- **ePI(L) benefits** patients, HCPs, industry, authorities, environment
- **Technology** such as DMC offers opportunity
- **Legislative change** is happening in EU

- Close **collaboration** of all stakeholders to deliver on the vision

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Thank you

Questions or comments?

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