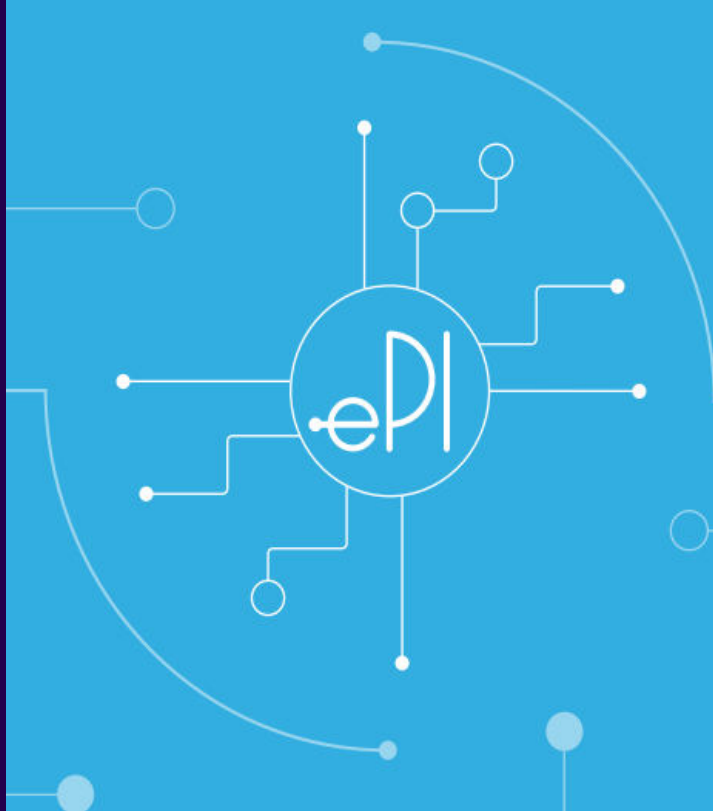


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# Electronic product information:

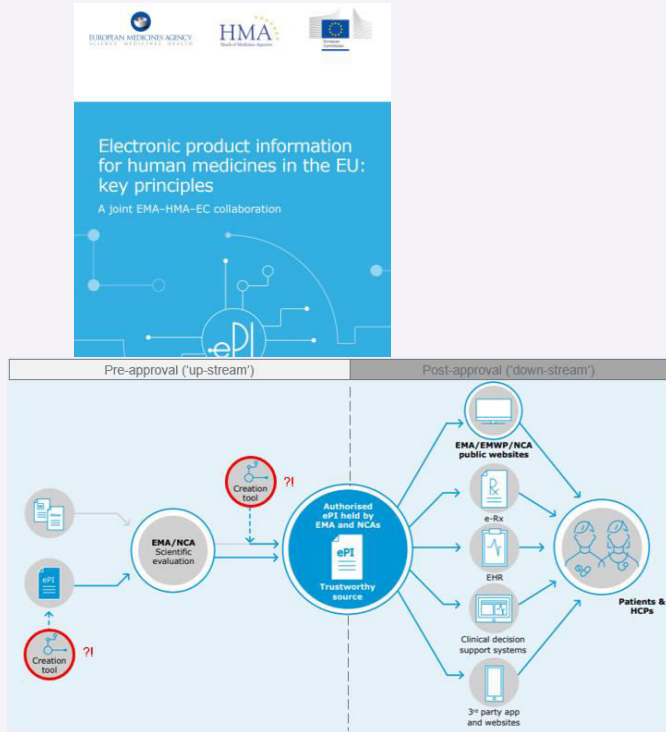
## Benefits and challenges

Sabine Faber

19 October 2023

Global Pharma Supply Chain & Logistics 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

# 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

# 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

# The benefits of electronic product information

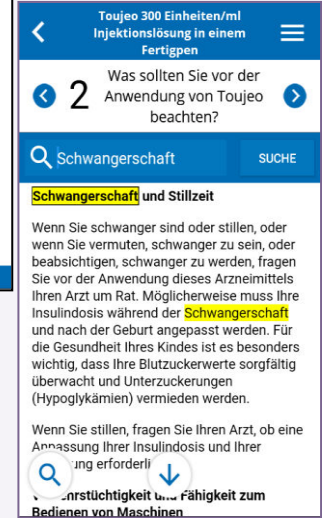
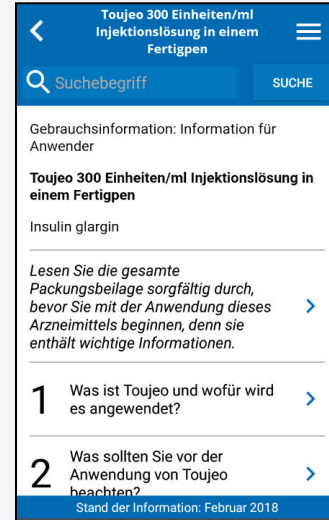
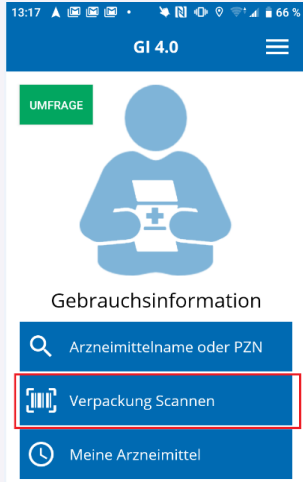


## For Environment & Sustainability

If ePI replaces the PI(L)

- Reducing waste
- Reducing consumption of paper and ink
- Contribution to green foot print

# German GI 4.0<sup>®</sup> 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

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

# 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`)\*:





# 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)



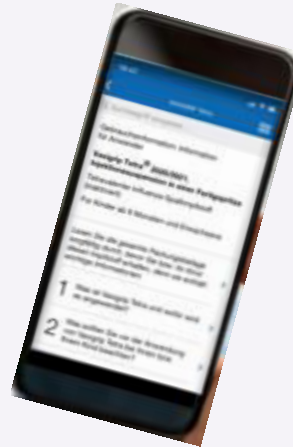
Technical solutions for easy access of DMC (e.g. without app) should be developed!

(QR codes available for interim phase)

# The challenges of electronic product Information

What is needed to get there?

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



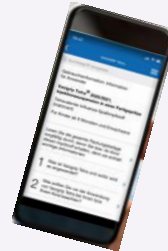
# In conclusion

## What is needed to get there?

- **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

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Questions or  
comments?



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