

Electronic dissemination of Product Information

Working together to
deliver e-Product Information to EU citizens and

enhance the capacity to make sound health decisions in the context of everyday life -
(digital) health literacy

Dr. Gesine Bejeuhr

Why ePI: Up-to-date, accurate information everywhere; Understandable, user-friendly and relevant



Trusted (Regulator-approved)/Non commercial



Real time and up-to-date information



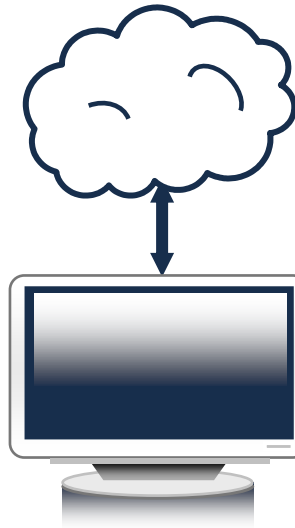
User friendly

- easy to navigate,
- available in the formats people prefer (electronic AND paper)
- different font sizes
- searchable



Understandable

(content appropriate to level of literacy)



Tailored / Relevant/ Responsive
(languages / tools, e.g. video, audio etc.)



Combine regulator-approved materials

(package leaflets*), educational material, lay summaries of EU public assessment reports/Risk Management Plans/ Clinical Trial Reports)



Can be used with e-prescription

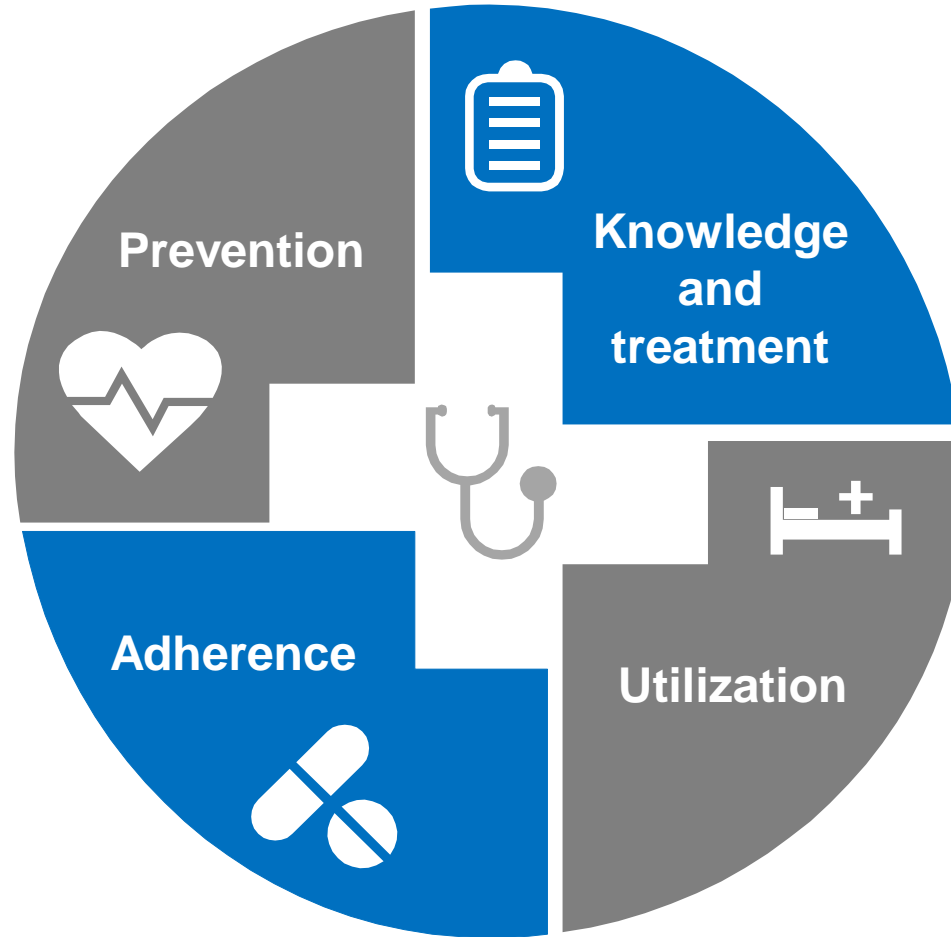
and medication reminders / other eHealth applications

*) same principle applies for Summary of Product Characteristics and other materials intended for Health Care Professionals

Why ePI: Improved access leads to better Health literacy – Supports empowerment of citizens

Earlier interactions /
better chances

Better understanding
why and how to take
medicines



Ability to ask questions;
Better knowledge of
conditions / optimal
management

Prevention of hospital
admissions / Emergency
Department visits

1. Nielsen-Bohlman, L., Panzer, A. M., & Kindig, D. A. (Eds.). (2004). *Health literacy: A prescription to end confusion*. Washington, DC: National Academies Press.
2. Weiss BD. *Health Literacy: Health literacy and patient safety: Help patients understand*. The American Medical Association (AMA) Foundation and the AMA. May 2007.
3. Wilson IR, et al. "Physician-Patient Communication About Prescription Medication Nonadherence: A 50-State Study of America's Seniors." JGIM. January 2007;22(1):6-12.

Industry needs / prerequisites for improved access for citizens

Consider evolving techn. environment

increasing use of mobile devices and electronic assistants and changing habits to produce agile solutions / guidance

Content formats/e-authoring principles

(e.g. e-QRD-template as "style guide"; structured data)

Packaging requirements for hospitals

paperless for hospital-only products / administered by a Health Care Professional, e.g. vaccines / other injectables

Use of existing infrastructure

cost effective and quicker implementation



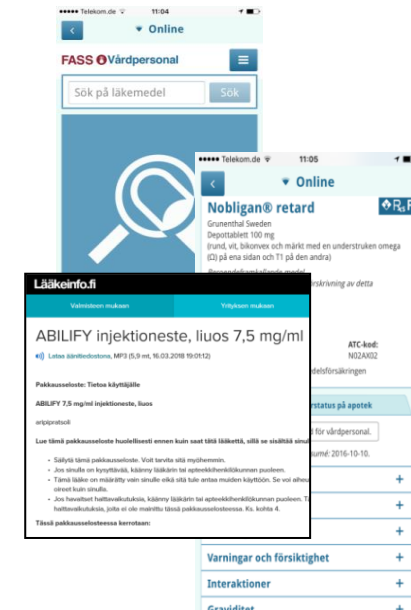
Technical requirements

- Interoperable links /unique keys (product's master data), e.g. in Falsified Medicines Directive, EMA SPOR project etc
- Well-accepted data carriers on the package for scanning (use of existing packages)
- Secure access (data input) prevention of source interference
- Data privacy (citizens) support up-to-date data safety standards
- Ensuring interoperability use of harmonized open and international exchange standards

The future should be sustainable

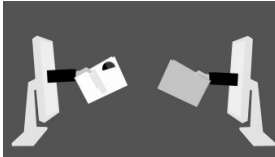
- ❑ **Experience with national databases**
e.g. AEMPS, FASS, Felleskatalogen, Rote Liste, eMC, Pharmadati
- ❑ **EU Telematics projects / EU eHealth strategy**
to reduce data redundancy; to ensure interoperability with EMA/HMA/Industry joint projects
- ❑ **Support Pharmacovigilance activities with harmonised structured data** from industry, agency, patients and back to the agency
- ❑ **Advanced technical solutions for Regulator-approved information to be competitive with other information providers**
for safeguarding correct and safe use of medicines according to accurate, up-to-date ePI
- ❑ **Stepwise approach towards use & acceptance of electronic product information**

More than 80% of EU Citizens search for health-related information on the internet (eurodis.org)



EU eHealth strategy is setting the future direction: The future label will not look like the label we know today

ePI
from multiple
medicines



Electronic
Medical
Records

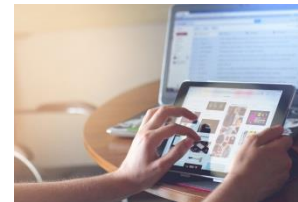


Health
Literacy
Materials



*Evaluation of risk
minimisation
activities*

*Artificial Intelligence;
machine-learning
algorithms*



Push

Pull

Personalised information
Optimised dosing
regimen
Multichannel output
Tailored key points

Push Alerts
Pull adverse drug
reactions
Real life Patient Use
Data aggregation

Working together to deliver eProduct Information to EU citizens and enhance digital health literacy



ePI supports citizens in every-day health care experience and **supports citizens' empowerment** through increased health literacy

ePI should be one of the **Telematics priorities** - shape regulatory framework to enable interoperable **digital innovations**

Sustainable solutions to assure ongoing effectiveness in the applied technical standards in a **rapidly transforming environment**

Involvement of stakeholders in standards / guidelines development