

## Joint statement on ePI



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# Outline

- Policy context
- Why Paper Package Leaflets matter?
- Balancing ePI benefits and challenges
- Patient privacy and data protection
- Final call for action

*\* Please see the full joint statement [here](#)*

# Policy context

- Background
  - European Commission's proposal for the revision of the EU pharmaceutical legislation
  - The proposal includes Electronic Product Information (ePI) for medicines
- Joint statement
  - Signataires: CPME, PGEU, BEUC, AGE, HOPE, AIM, EFN, EAHP, EPF
  - Call for Action: **Maintain paper package leaflets and use ePI as a complementary tool**

# Why Paper Package Leaflets matter?

- **Access to Complete & Unbiased Information**
  - Package leaflet is a vital component of the information provided to patients on the safe and effective use of the medicines they take, which is a consideration under the benefit/risk analysis
- **Health literacy**
  - Paper leaflets help improve health literacy and empower patients to make informed decisions about the medicines they take
- **Inclusivity**
  - Important for people who may not have access to smartphones or the internet, or choose not to use them (due to age, geographical location, disability, health, income, religion or social situation)
- **Research & Evidence**
  - Studies conducted in other fields show that a low level of consumers scan product information made available through a QR Code

# Balancing ePI benefits and challenges

- **Potential benefits of ePI**
  - When developed in close collaboration with patients and healthcare professionals, ePI offers opportunities to improve readability and meet specific patients' needs (such as those with impaired sight)
- **Challenges**
  - Digital Divide: ePI requires access to smartphones, internet, and data plans – not accessible to all patients
  - Access Issues: internet connectivity issues in hospitals, rural areas and during emergencies could prevent access
- **Cost Implications**
  - Pharmacists and patients may bear costs of printing leaflets if those are not provided in the package

# Protecting patient privacy and data protection

- **Data privacy risks**
  - ePI should not compromise patient privacy: third-party links should not store personal information
  - Ensure that patient data is not used for commercial purposes or promotional activities
- **Compliance with legislation**
  - Strict adherence to the EU General Data Protection Regulation is essential for any platform accessing ePI
- **Official sources**
  - Official sources: ensure ePI is accessed from trusted sources (e.g., EMA, NCAs websites)

# Final Call to Action

- **Inclusive Access for All**
  - Inclusive Access for All: paper leaflets should remain available for those who prefer them or cannot use ePI, so it's **essential to Keep Paper Leaflets, and use ePI as a complementary tool**
- **Choice and empowerment for patients**
  - Maintain digital and non-digital options so patients can choose based on personal preference or needs
- **Guarantee Privacy**
  - Ensure strong privacy safeguards for patients accessing ePI information

**Call on legislators to maintain paper package leaflets, and use electronic leaflets as a complementary tool!**

# Thank you for your attention

For more information, please contact CPME Secretariat:

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