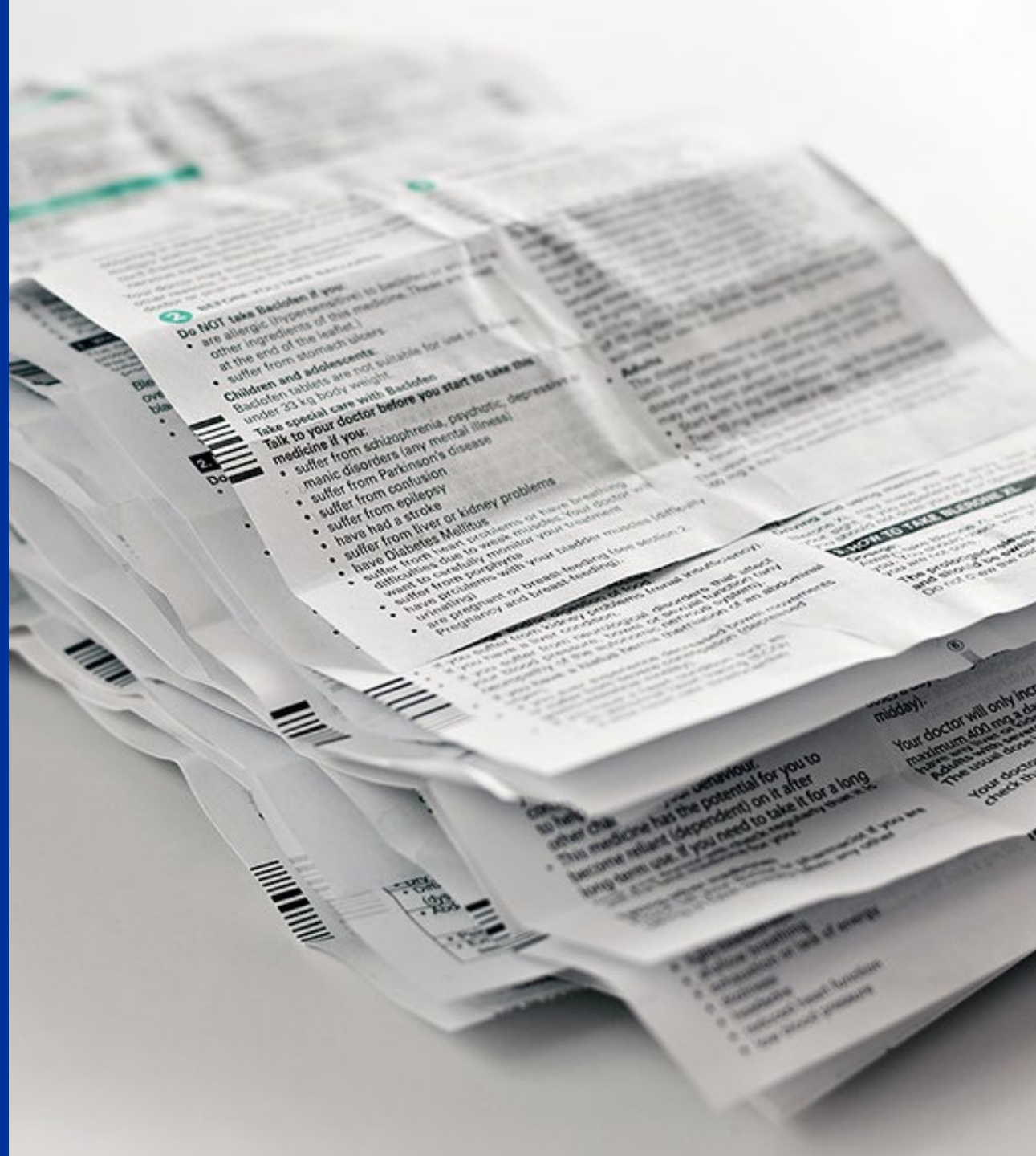
EMA
EUROPEAN MEDICINES AGENCY

Update of the QRD template Package Leaflet revision

Joint PCWP and HCPWP meeting

1 April 2025

Presented by Monica Buch - EMA Labelling Office



Background

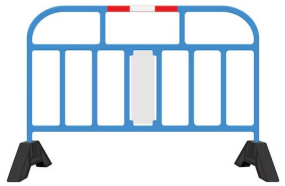
- Human QRD Template for product information
  - Created in 1996, rather stable (10 versions in 29 years), last major revision in 2011
- EC's report on shortcomings in PI (2017) → **recommendation to improve PL**
  - Electronic PL/SmPC formats → ePI will change provision of PLs
  - Room for improvement of PL
  - Amendments of Guidelines and QRD templates to enhance readability of PL
  - Potential **key information section in PL** and SmPC
  - Improving patient input in developing/testing PLs and promotion/exchanges of best practice
- EMA Labelling Office + NCAs experience + Feedback from readability companies + Voice of patients/consumers/HCPs + Industry's work on PL improvement

PL improvement project (initiated in September 2023)

PL improvement project outline

- **July 2023** – Approval from EMA management at Regulatory Forum
- Creation of QRD working subgroup (EMA LAB + QRD MSs + PCWP/HCPWP reps)
- QRD working subgroup meetings
- Discussion of comments and proposals with QRD Group
- Consultations with QRD-Industry platform members
- Regular updates to PCWP/HCPWP – ***last one July 2024***
- Final proposal agreed by QRD subgroup and endorsed by QRD Group

  → **Main change: inclusion of Key information section**
- Revised QRD template v11 ready for public consultation **– October 2024**



Discussions around the inclusion of the 'key information section'

Next steps

- Get final go ahead from the European Commission
- Release proposed QRD template for public consultation
- User testing during public consultation
- Assessment comments received from public consultation
- Assessment of user testing results
- Discussions within QRD subgroup and QRD Group
- Final discussion at a multistakeholders workshop
- Final adoption by the QRD Group
- Translation process and publication

ePI Project
New Pharma Legislation

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Thank you

monica.buch@ema.europa.eu

qrd@ema.europa.eu

Follow us