EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

QRD Template revision
Improvement of package leaflet

PCWP/HCPWP joint meeting – 19 September 2023

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Background

- Human QRD Template for product information
  - Created in 1996
  - Content bound by legislation
  - Same package leaflet (PL) structure since 1998
  - Very stable throughout → 10 versions in 27 years
  - Last major revision in 2011

→ QRD Human PI Annotated Template v10.3 (europa.eu)

Drivers for PL template revision

- EC's report on shortcomings in product information → *recommendations*
  - Electronic PL/SmPC formats *(prioritised)* → **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 and testing of PLs
  - Promotion and exchanges of best practice
- EMA Labelling Office / NCAs experience
- Feedback from readability companies ~ voice of patients/consumers/HCPs
- Industry's work on PL improvement
- End of BCP and pandemic, outline of pharma legislation revision, resources reallocation

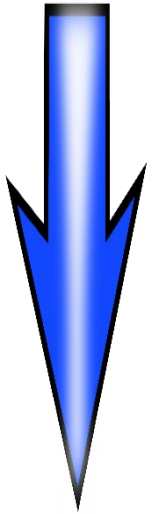
Overview of main changes

- Shortening length of PL
  - ✓ Less paper, environmental gains
  - ✓ Bigger font size, better readability
  - ✓ Facilitate multilingual PLs
  - ✓ Motivate patients/users to read
- Increase flexibility (within legal framework boundaries)
- Improve patient-friendliness
- Focus on patient relevant content
- Explore inclusion of a key information section
- Include information on benefits, more positive messages

Project outline

- Creation of a QRD working subgroup
- Get approval from EMA management
- Identify PCWP/HCPWP representatives to be part of the subgroup
- Prepare initial proposal for discussion with QRD Group
- Consultations with QRD-Industry platform members
- Release proposed revised template for public consultation
- Assess comments received from public consultation
- Prepare proposal to be discussed with all stakeholders (workshop)
- Proposal agreed after workshop to be endorsed by QRD Group
- Publish revised QRD template (with implementation period)

June 2023



December 2024

QRD subgroup – Composition and work

- Composition:
  - ✓ 9 QRD members → CZ, DE PEI, FI, IT, LV, MT, NO, RO, SV
  - ✓ EMA Labelling Office → QRD Group Chair and Senior Labelling Specialist
  - ✓ EMA Stakeholders & Public Engagement Dept → one Medical Writer and one Patient Liaison
  - ✓ PCWP/HCPWP representatives: one Patients rep, one Consumers rep, one HCPWP rep
- Iterative meetings and/or exchange of written comments
- Discuss proposals with Industry in the context of the QRD/Industry Platform
- Keep QRD Group informed via QRD Plenary meetings
- Assessment of comments from public consultation
- Workshop with all stakeholders in 2024
- Present final QRD template to QRD Group for endorsement

QRD subgroup members – Expected contribution

- Participation in meetings
  - ✓ Attend all meetings of the subgroup (virtual, monthly or bi-monthly as needed)
  - ✓ Attend meetings with Industry (virtual, in the context of the QRD/Industry platform)
  - ✓ Attend multi-stakeholder workshop in 2024 (in person, date tbc)
- Contribute to the exchange of written comments, if/when needed
- Get familiar with the QRD template, reference documents and legal requirements
  → Product-information requirements | European Medicines Agency (europa.eu)
- Gather views of their respective groups so they are reflected in the discussions
- Raise as many proposals for improvement as possible, based on experience/expertise

Any questions?

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