



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Review of package leaflet (PL) template Update on QRD subgroup on PL improvement

PCWP/HCPWP joint meeting – 28 February 2024

Presented by Monica Buch
Senior Labelling Specialist
EMA Labelling Office (H-Q-LAB)

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Project development to date

- 13/10/2023 → First full QRD subgroup meeting
- 06/11/2023 → QRD subgroup joins QRD/Industry meeting to present initial proposals
- 24/11/2023 → Industry provides written comments
- 07/12/2023 → PCWP/HCPWP representatives gather PL users views via survey
- 11/12/2023 → QRD subgroup meets to discuss comments
- 18/12/2023 → QRD subgroup meeting outcome sent to Industry
- 01/02/2024 → Industry provides written comments
- 08/02/2024 → Survey sent via PCWP/HCPWP representatives to gather PL users views on
 - the potential **key information section**
 - the presentation of **benefits/risks**



Next steps

- 29/02/2024 → PCWP/HCPWP **Survey** deadline
- 07/03/2024 *QRD Plenary meeting*
- March 2024 → **QRD subgroup meeting** to discuss Industry's comments and survey results
- Contingency time for further reflection/discussion on **controversial points**:
 - ✓ **key information section** ➤ divergent views
 - ✓ **benefits/risks balance** ➤ how best present it
 - ✓ other
- April-May 2024 → meeting QRD subgroup and Industry subgroup
- 26/06/2024 **QRD Plenary meeting** → tentative adoption of draft template?



Project further development

➤ Remaining work

- ✓ Adoption revised QRD template by QRD Group
- ✓ **Public consultation**
- ✓ Assessment of comments received
- ✓ Further discussions within relevant fora (QRD subgroup/Industry/EMA/QRD Group)
- ✓ **Multi-stakeholder workshop**
- ✓ Further discussions within relevant fora (QRD subgroup/Industry/EMA/QRD Group)
- ✓ **Potential user testing of proposed PL template**
- ✓ Adoption of final QRD template
- ✓ Translations and publication



Project further development

➤ Dependencies/Caveats

- Comments received during public consultation
- Outcome of multi-stakeholder workshop
- Need to liaise with EC on their recommendations
- Findings from user testing of proposed PL template
- Development of other projects running in parallel
- Other eventualities



Thank you

Further information

monica.buch@ema.europa.eu / qrd@ema.europa.eu

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Telephone +31 (0)88 781 6000

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