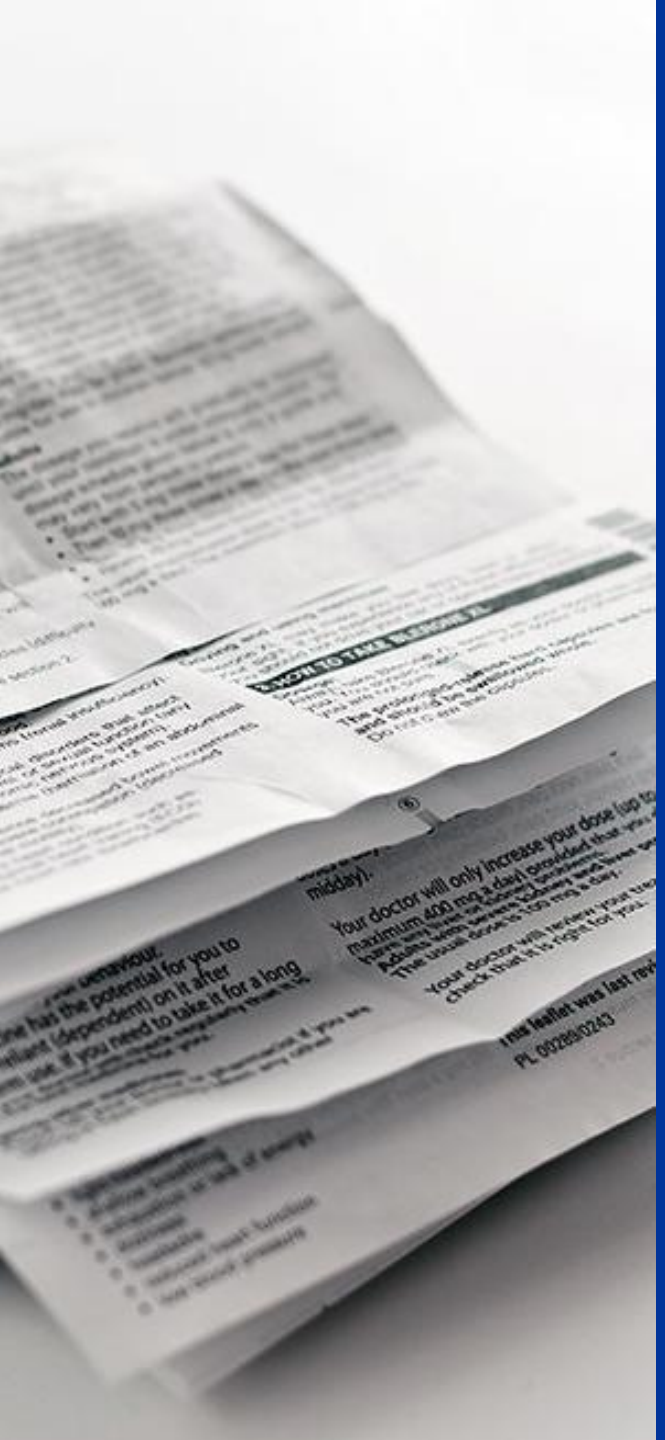

Update on QRD template revision

Industry platform meeting

Monica Buch (Labelling Office)

20 November 2026

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QRD template revision

Progress to date

1 Approval and setup

PL improvement project

EMA management approval

QRD subgroup setup (EMA, QRD PCWP/HCPWP)

2 Joint development

QRD subgroup meetings and QRD Group discussions

QRD-Industry platform consultations and PCWP/HCPWP updates

3 Proposal and adoption

QRD subgroup agreement and QRD Group endorsement

Key Information Section proposed but rejected by EC

Revised QRD template v11 released for public consultation

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QRD template revision

Progress to date

4

Consultation and assessment

4-month public consultation

≈800 comments from 40 stakeholders

EMA LAB assessment

5

QRD Group discussion

Discussion of outstanding comments

Remaining unresolved comments

QRD Stakeholders workshop

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QRD template revision

QRD Stakeholders workshop

27th November 2026, EMA premises

Attendees:

QRD members and other NCA regulators

Representatives of PCWP & HCPWP

Industry associations delegates

Other participants

Topics:

Background and context

Resolving outstanding comments

Review of implementation plan

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QRD template revision

Next steps

27 November 2026 — Estimated timeline (indicative) — **End Q1 2027**



QRD Stakeholders workshop

- *If all outstanding comments resolved and draft QRD template v11 agreed*

Adoption by QRD Group

Translation process

Publication and implementation

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QRD template revision

Implementation plan

- **Considerations for a flexible implementation approach**

Standard implementation
(no strict legal date)

- Immediately for new MAAs
- 3-4 years for existing MAs

EMA is carefully considering

Upcoming NPL implementation

ePI project

Historical stability of QRD template versions

Implementation approach to be discussed at the workshop

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Thank you

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