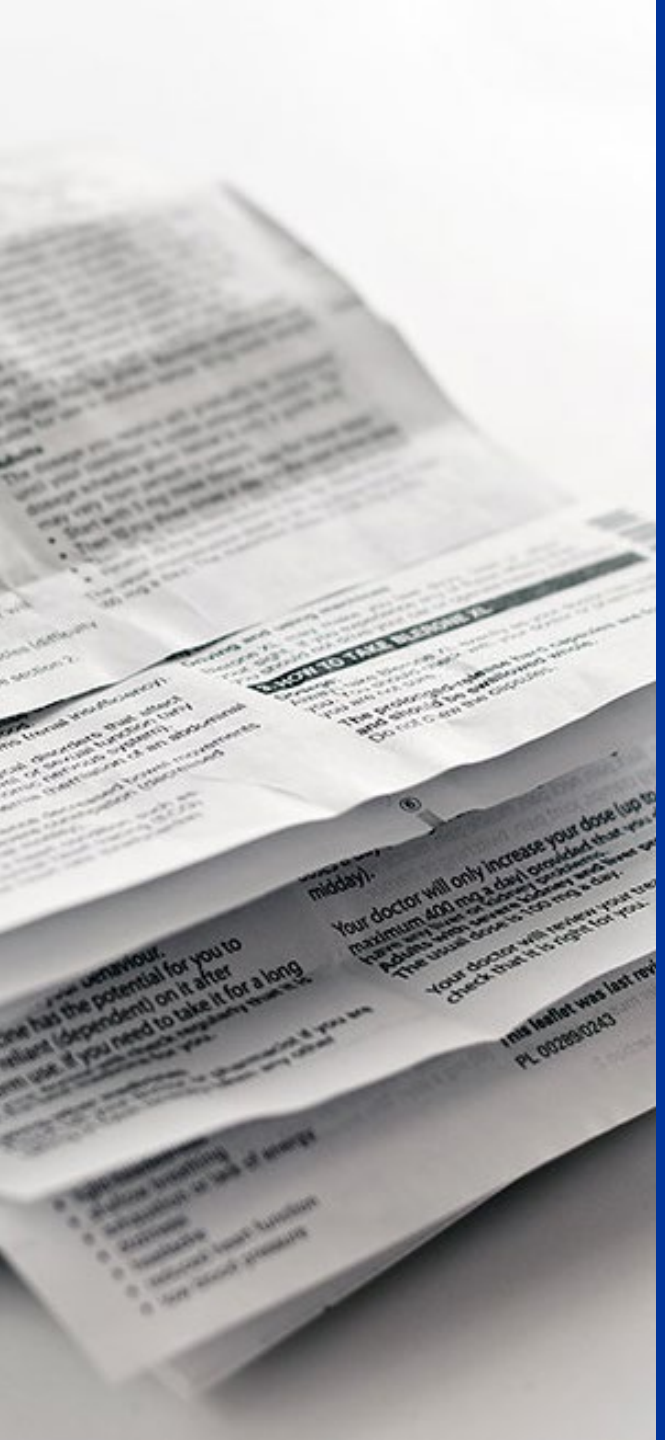


Update on QRD template revision and ‘Key information section’ (KIS) survey

PCWP/HCPWP and all eligible organisations meeting

Monica Buch (Labelling Office)

19 November 2025

EMA
EUROPEAN MEDICINES AGENCY

External consultation on draft QRD template v11

QRD template version 11

Version 11 of the **quality review** of **documents** (QRD) template was available for public consultation.

EMA is revising the QRD template for centrally authorised medicines for human use mainly to improve the content and structure of their package leaflet.

This aims to make the package leaflet more understandable and relevant to patients, while complying with the current legislative framework, Directive 2001/83/EC .

Main proposed changes include:

- Deleting or making certain text optional to shorten the leaflet
- Creating standard statements to improve patient-friendliness and consistency across products
- Relocating important information at the beginning of the leaflet
- Clustering information by subject to make it easier to locate
- Reorganising warnings / precautions in a more logical order

Stakeholders invited to comment on the draft QRD template v11 included the pharmaceutical industry, national competent authorities, patients, healthcare professionals and academia.

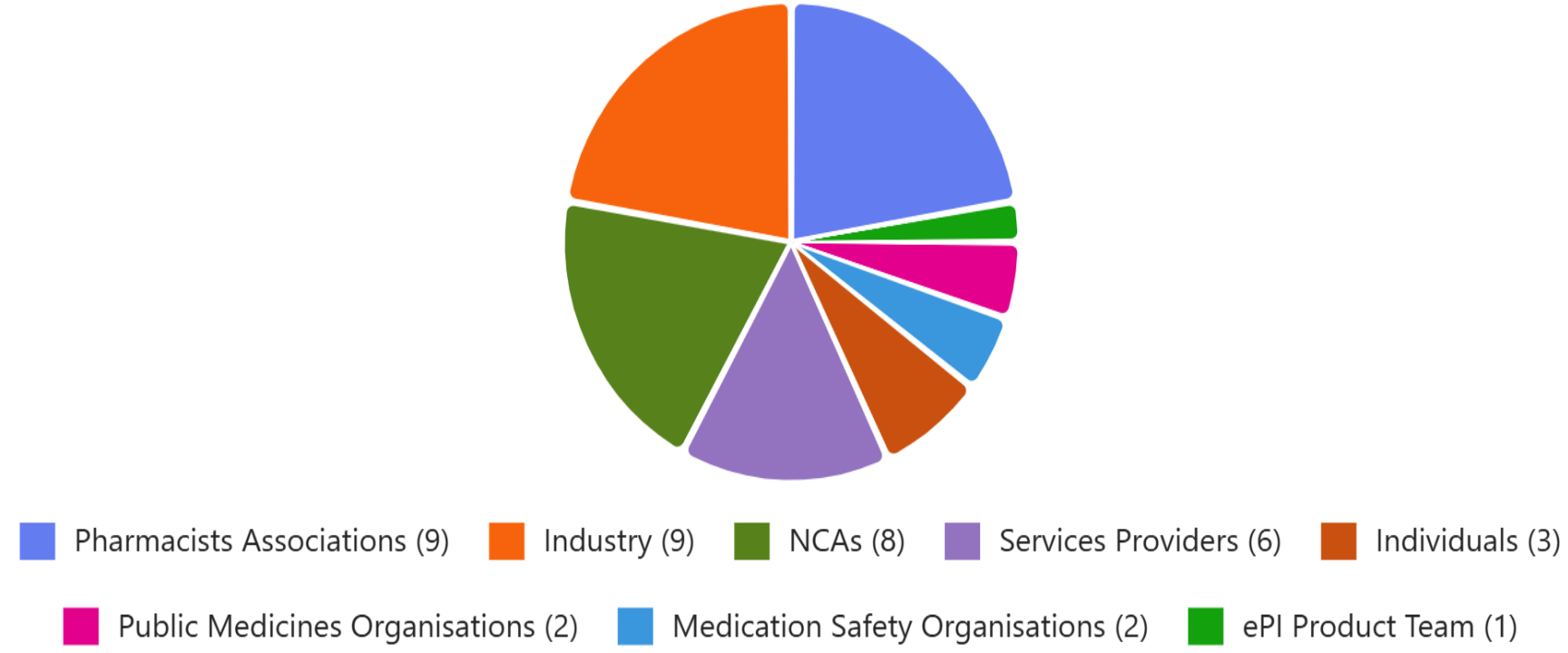
Find below the draft template, in both clean and track change versions.

Quality Review of Documents (QRD) annotated template v11: Draft for public consultation

Draft: consultation closed
Consultation dates: 14/04/2025 to 31/08/2025
Summary: The ongoing revision of the QRD template started in September 2023, mainly triggered by the Report from the Commission to the European Parliament and the Council in accordance with Article 59(4) of Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use. This report is an assessment of shortcomings in the summary of product characteristics (SmPC) and the package leaflet (PL), and it provides some recommendations on how they could be improved to better meet the needs of patients and healthcare professionals.

In addition, the revision has also considered the extensive experience gained over the years by the EMA Labelling Office and the QRD members, the voice of patients, consumers and healthcare professionals, the feedback provided by stakeholders performing consultation with target patients' groups (so called user testing), and the work performed by some industry stakeholders on the improvement of the PL.

- External consultation launched on 11th April 2025
- Published alongside the survey on ‘key information section’ in the PL
- Consultation closed on 31st August 2025
- **≈800 comments from 40 stakeholders**



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Consultation on ‘Key information section’ (KIS) in Package Leaflet

Public survey results

Package leaflet key information

EMA enabled stakeholders to comment on a public consultation on the potential inclusion of a ‘key information section’ in the **package leaflet** of centrally authorised medicines.

A ‘key information section’ section would allow patients and healthcare professionals, among others, to:

- rapidly identify key safety messages;
- and find information on the benefit-risk profile of medicines.

The public consultation concluded on 31 May 2025.

Key information section in package leaflet of centrally authorised medicinal products: Public consultation

Draft: consultation closed

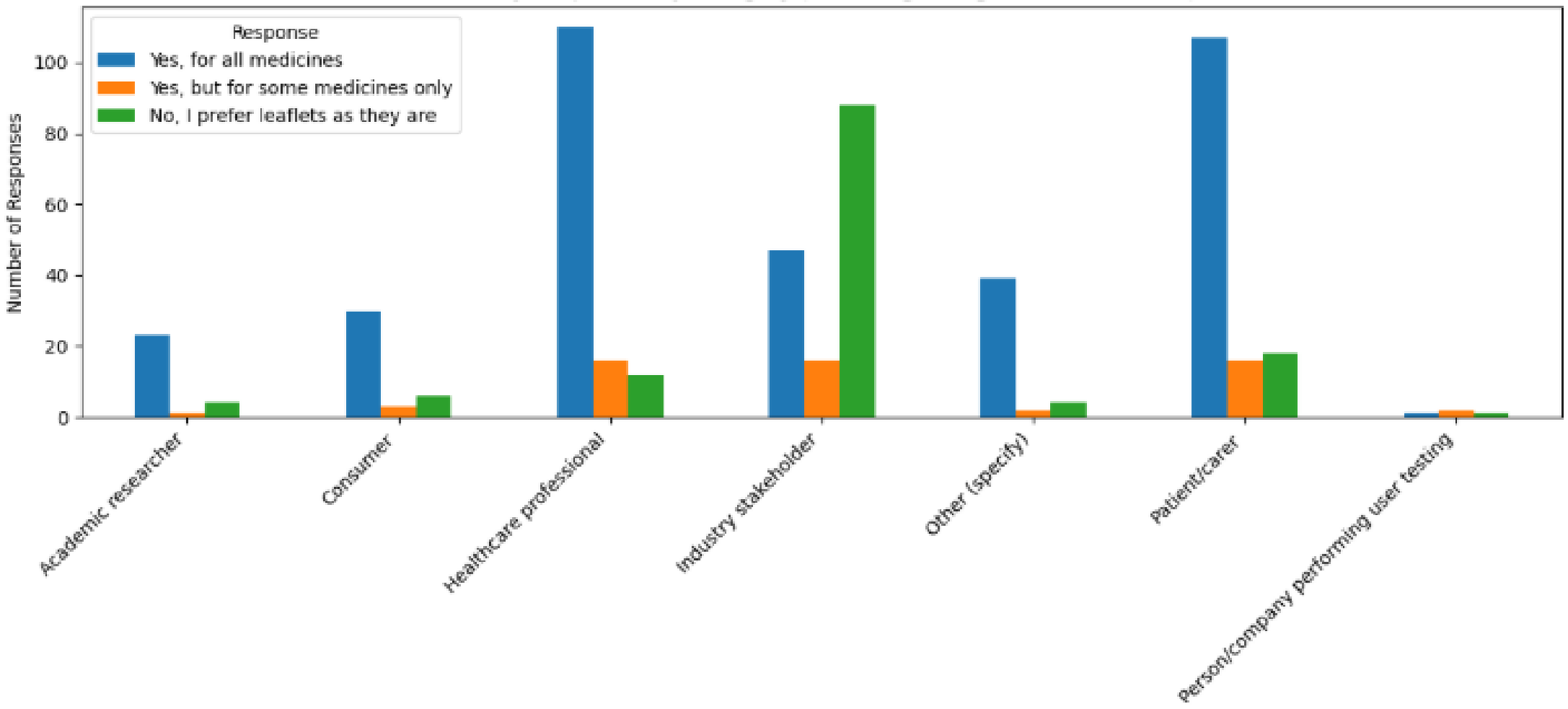
Consultation dates: 14/04/2025 to 31/05/2025

English (EN) (117.25 KB - PDF)

First published: 14/04/2025

View

- Consultation agreed with European Commission on 7 April
- EU Survey open for public consultation 11 April – 31 May
- **561 answers received**
  - **413 in favour** (357 for all medicines + 56 for some medicines)
    - 282 patients/consumers/HCPs
    - 63 industry
    - 44 other
    - 24 academia
  - **133 against**
    - 90 industry
    - 36 patients/consumers/HCPs
    - 7 other
  - 15 no opinion

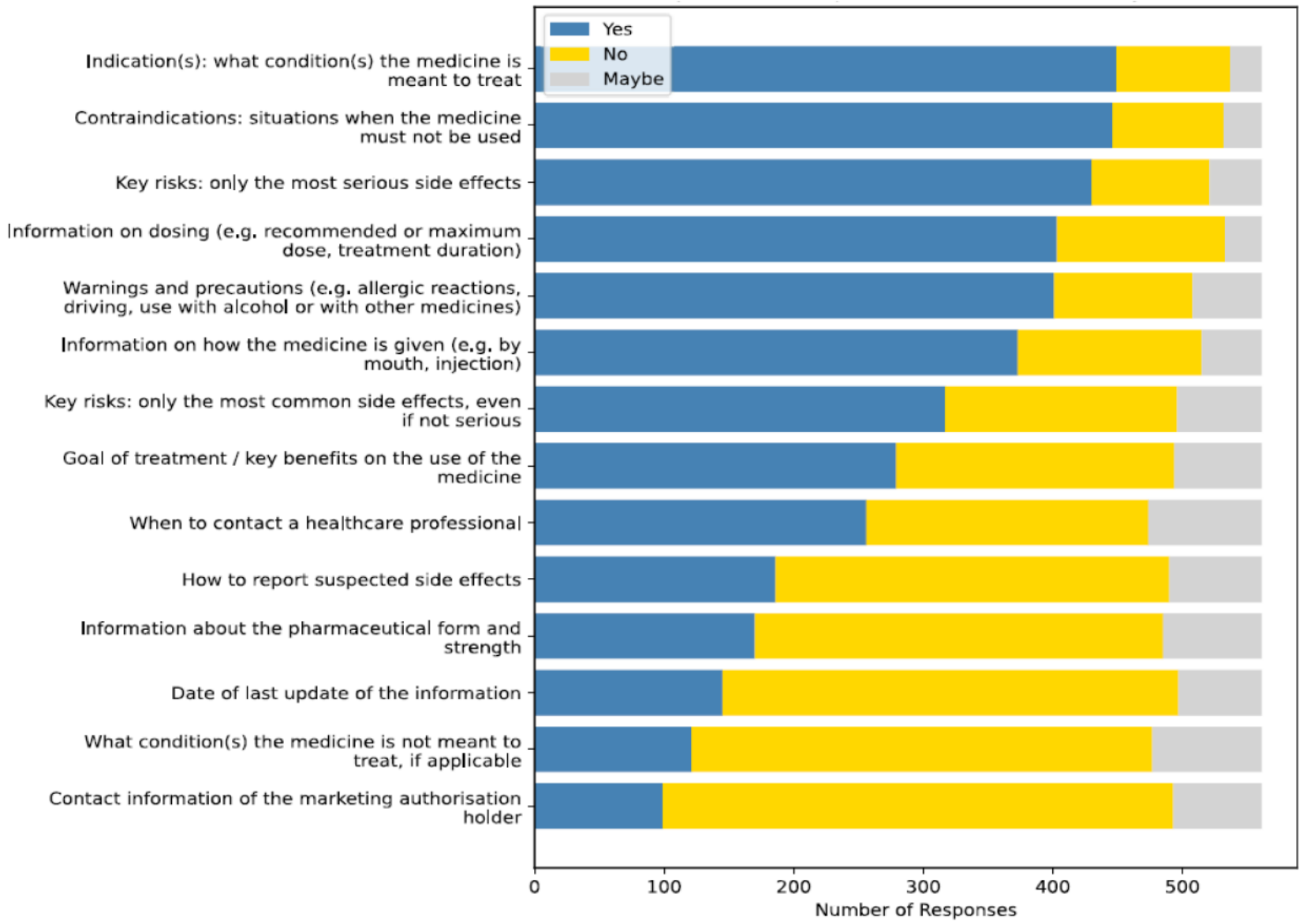


- Concern that KIS can make package leaflet (PL) **longer**?
  - ✓ 40.46% YES
  - ✓ 56.68% NO
  - ✓ 2.85% not sure / no opinion

- Concern that users may **read KIS only** and skip rest of PL?
  - ✓ 78.43% YES
  - ✓ 16.76% NO
  - ✓ 4.81% not sure / no opinion

  Comments:
    - ✓ Need for a disclaimer
    - ✓ Beneficial compared to reading nothing

➢ Information to be included in KIS?



Arguments in favour of KIS

- ✓ Improved comprehension and clarity
- ✓ Enhanced accessibility and navigation
- ✓ Conciseness and focus
- ✓ Support for informed decision-making
- ✓ Alignment with modern communication practices

Arguments against KIS

- ✓ Increased length, complexity and redundancy
- ✓ Subjectivity in defining “key”
- ✓ Risk of oversimplification, misinterpretation and misinformation
- ✓ Implementation and regulatory burden
- ✓ Legislative requirements or legal concerns
- ✓ Lack of supporting evidence
- ✓ Electronic product information (ePI) as alternative

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Thank you

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