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Labeling Office

Consultation on a potential Key Information Section in the Package Leaflet of centrally authorised medicinal products

Start of public consultation	11 April 2025
End of consultation (deadline to respond to survey)	31 May 2025

Comments should be provided using this EU Survey form by 31 May 2025. For any technical issues, please contact the EU Survey Support.

Keywords	*QRD, template, key information section, package leaflet*

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The European Medicines Agency (EMA) and the Quality Review of Documents (QRD) Working Group are currently working on the revision of the QRD template for centrally authorised medicinal products for human use, with the aim of improving the content and structure of the package leaflet and making it more understandable and relevant to patients, while still complying with the current legislative framework. The draft revised QRD template has been released for public consultation until 31 August 2025 and

Separate from the public consultation of the QRD template, which can be accessed here, the EMA would like to gather the views of stakeholders on the potential usefulness and added value of a new "key information section" in the package leaflet. The addition of this new section addresses one of the recommendations in 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*, and it would allow patients, users and healthcare professionals to rapidly identify key safety messages, balanced with information on the benefit-risk profile of the medicine.

As concluded in the report, the evidence and views collected may help inform the decision on whether such a key information section in the package leaflet is needed and, if so, what type of information should be provided therein.

Therefore, the EMA would like to invite all interested stakeholders to respond to this survey **by 31 May 2025.**

Thank you very much in advance for your contributions.