



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

26 November 2025  
EMA/632790/2019 Rev. 6\*  
Human Medicines Division

## Expected publication dates of PRAC recommendations on safety signals

When PRAC has recommended a product information update, marketing authorisation holders (MAHs) are expected to submit the requested variation according to the timeline specified in the PRAC recommendation. This timeline is calculated from the date of publication of the PRAC recommendation. Expected dates of publication can be found below. The actual date of publication is always mentioned on the EMA website just below the published document.

This timetable may be subject to revisions.

PRAC dates	Expected publication dates of PRAC recommendations on safety signals
24-27 November 2025	6 January 2026
12-15 January 2026	9 February 2026
9-12 February 2026	9 March 2026
9-12 March 2026	7 April 2026
7-10 April 2026	4 May 2026
4-7 May 2026	1 June 2026
8-11 June 2026	6 July 2026
6-9 July 2026	3 August 2026
31 August – 3 September 2026	28 September 2026
28 September – 1 October 2026	26 October 2026
26-29 October 2026	23 November 2026
23-26 November 2026	5 January 2027

\* Revision 6 includes dates for 2026.

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