



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2025
EMA/632790/2019 Rev. 5* Corr[†]
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 revision.

PRAC dates	Expected publication dates of PRAC recommendations on safety signals
25-28 November 2024	7 January 2025
13-16 January 2025	10 February 2025
10-13 February 2025	10 March 2025
10-13 March 2025	7 April 2025
7-10 April 2025	5 May 2025
5-8 May 2025	2 June 2025
2-5 June 2025	30 June 2025
7-10 July 2025	11 August 2025
1-4 September 2025	29 September 2025
29 September – 2 October 2025	27 October 2025
27-30 October 2025	24 November 2025

* Revision 5 includes dates for 2025.

[†] The expected publication date of the PRAC recommendations on safety signals adopted at the 7-10 July 2025 PRAC has been postponed from 4 August to 11 August 2025.



PRAC dates	Expected publication dates of PRAC recommendations on safety signals
24-27 November 2025	6 January 2026