



1 December 2023  
EMA/632790/2019 Rev. 4\*, Corr 1<sup>†</sup>  
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
27-30 November 2023	5 January 2024
8-11 January 2024	5 February 2024
5-8 February 2024	4 March 2024
4-7 March 2024	2 April 2024
8-11 April 2024	6 May 2024
13-16 May 2024	10 June 2024
10-13 June 2024	8 July 2024
8-11 July 2024	12 August 2024 <sup>‡</sup>
2-5 September 2024	30 September 2024
30 September – 3 October 2024	28 October 2024
28-31 October 2024	25 November 2024

\* Revision 4 includes dates for 2024.

<sup>†</sup> The publication date of the 8-11 July 2024 PRAC documents has been postponed to 12 August 2024.

<sup>‡</sup> Date postponed by one week to 12 August 2024.



<b>PRAC dates</b>	<b>Expected publication dates of PRAC recommendations on safety signals</b>
25-28 November 2024	6 January 2025