



21 November 2019
EMA/632790/2019
Inspections, Human Medicines Pharmacovigilance and Committees 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 2019	7 January 2020
13-16 January 2020	10 February 2020
10-13 February 2020	9 March 2020
9-12 March 2020	6 April 2020
14-17 April 2020	11 May 2020
11-14 May 2020	8 June 2020
8-11 June 2020	6 July 2020
6-9 July 2020	3 August 2020
31 August-3 September 2020	28 September 2020
28 September-1 October 2020	26 October 2020
26-29 October 2020	23 November 2020
23-26 November 2020	6 January 2021

