



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

30 August 2022
EMA/PRAC/51714/2021 Rev.5

Timetable for the procedure

Referral under Article 31 of Directive 2001/83/EC resulting from pharmacovigilance data

Amfepramone-containing medicinal products

Procedure no: EMEA/H/A-31/1501

Procedural step:	Date
Notification:	25 January 2021
Start of the procedure (PRAC):	February 2021 PRAC
List of questions:	11 February 2021
Submission of responses:	10 May 2021
Re-start of the procedure:	10 June 2021
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	16 June 2021
Comments:	23 June 2021
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh	29 June 2021
PRAC list of outstanding issues:	08 July 2021
Submission of responses:	08 September 2021
Re-start of the procedure:	29 September 2021

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human

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Procedural step:	Date
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	05 October 2021
<i>Ad-hoc</i> expert group meeting:	11 October 2021
Comments:	13 October 2021
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh	19 October 2021
PRAC list of outstanding issues:	28 October 2021
Submission of responses:	15 April 2022
Re-start of the procedure:	12 May 2022
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	16 May 2022
Comments:	23 May 2022
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh	3 June 2022
PRAC recommendation to CMDh:	10 June 2022
Re-examination - receipt of letter of intent from MAH:	11 July 2022
Re-examination - receipt of detailed grounds from MAH:	29 August 2022
Re-examination - start of re-examination procedure:	30 August 2022
Re-examination - rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	29 September 2022
Re-examination - comments:	6 October 2022
Re-examination - joint assessment report:	14 October 2022
Re-examination - PRAC final recommendation:	November 2022 PRAC
CMDh position:	November 2022