28 September 2023
EMA/PRAC/55340/2023 Rev. 3

Timetable for the procedure

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

Pseudoephedrine-containing medicinal products

Procedure no: EMEA/H/A-31/1526

Aerinaze EMEA/H/A-31/1526/C/000772/0047

Procedural step:	**Date**
Notification:	03 February 2023
Start of the procedure (PRAC):	February, 2023 PRAC
List of questions:	09 February 2023
Submission of responses:	24 March 2023
Re-start of the procedure:	14 April 2023
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]:	21 April 2023
Comments:	28 April 2023
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	05 May 2023
PRAC List of outstanding issues:	12 May 2023
Submission of responses:	03 August 2023

[1] Committee for Medicinal Products for Human Use

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Procedural step:	**Date**
Re-start of the procedure:	31 August 2023
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	08 September 2023
Ad-hoc Expert meeting (AHEG):	14 September 2023
Comments:	15 September 2023
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	21 September 2023
PRAC 2nd list of outstanding issues	28 September 2023
Submission of responses:	19 October 2023
Re-start of the procedure:	02 November 2023
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	10 November 2023
Comments:	16 November 2023
Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	22 November 2023
PRAC list of outstanding issues or PRAC recommendation to CHMP:	December, 2023 PRAC