EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

05 May 2022
EMA/PRAC/522598/2021 – Rev. 2

Timetable for the procedure

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

Medicinal products containing nomegestrol or medicinal products containing chlormadinone

Procedure no: EMEA/H/A-31/1510

Zoely EMEA/H/A-31/1510/C/1213/60

Procedural step:	**Date**
Notification:	22 September 2021
Start of the procedure (PRAC[1]):	30 September 2021
List of questions:	30 September 2021
Submission of responses:	25 November 2021
Re-start of the procedure:	16 December 2021
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[2]:	21 January 2022
Comments:	28 January 2022
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	03 February 2022
PRAC list of outstanding issues:	10 February 2022
Submission of responses:	17 March 2022

[1] Pharmacovigilance Risk Assessment Committee
[2] Committee for Medicinal Products for Human Use

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Procedural step:	**Date**
Re-start of the procedure:	07 April 2022
Rapporteur/co-rapporteur joint assessment reports circulated to PRAC and to CHMP:	13 April 2022
Comments:	22 April 2022
Updated rapporteur/co-rapporteur joint assessment reports circulated to PRAC and to CHMP:	28 April 2022
PRAC list of outstanding issues or PRAC recommendation to CHMP:	05 May 2022
Submission of responses:	30 May 2022
Re-start of the procedure:	09 June 2022
Rapporteur/co-rapporteur joint assessment reports circulated to PRAC and to CHMP:	17 June 2022
Comments:	24 June 2022
Updated rapporteur/co-rapporteur joint assessment reports circulated to PRAC and to CHMP:	30 June 2022
PRAC list of outstanding issues or PRAC recommendation to CHMP:	July PRAC 2022