EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 June 2020
EMA/PRAC/121857/2020 Rev. 1

Timetable for the procedure

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

Ulipristal acetate 5mg medicinal products

Procedure no: EMEA/H/A-31/1496

Esmya EMEA/H/A-31/1496/C/2041/0049

Ulipristal Acetate Gedeon Richter EMEA/H/A-31/1496/C/5017/0002

Procedural step:	**Date**
Notification:	05 March 2020[1]
Start of the procedure (PRAC):	March 2020 PRAC meeting
List of questions:	12 March 2020
Submission of responses:	23 April 2020
Re-start of the procedure:	14 May 2020
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[2]:	20 May 2020
Comments:	27 May 2020
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	4 June 2020
PRAC list of outstanding issues:	11 June 2020

[1] a corrigendum superseding the initial notification was circulated to EMA/PRAC secretariat on 9th March 2020
[2] Committee for Medicinal Products for Human Use

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Procedural step:	**Date**
Submission of responses:	30 June 2020
Ad-hoc expert group meeting:	02 July 2020
Re-start of the procedure:	09 July 2020
Rapporteur/ co-rapporteur joint assessment report circulated to PRAC and to CHMP:	10 August 2020
Comments:	21 August 2020
Updated rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP	28 August 2020
PRAC recommendation:	September 2020 PRAC