



30 November 2017
EMA/PRAC/461927/2016 Rev. 3

Timetable for the procedure

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

Retinoids containing medicinal products

Procedure no: EMEA/H/A-31/1446

Panretin EMEA/H/A-31/1446/C/000279/0037

Targretin EMEA/H/A-31/1446/C/000326/0043

Procedural step:	Date
Notification:	7 July 2016
Start of the procedure (PRAC):	July 2016 PRAC
List of questions:	7 July 2016
Submission of responses:	30 September 2016
Re-start of the procedure:	03 November 2016
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP ¹ :	14 November 2016
Comments:	21 November 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	24 November 2016
PRAC list of outstanding issues:	28 November to 1 December, 2016 PRAC

¹ Committee for Medicinal Products for Human Use



Procedural step:	Date
Submission of responses:	01 March 2017
Re-start of the procedure:	07 April 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	18 April 2017
Comments:	25 April 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	28 April 2017
PRAC list of outstanding issues:	5 May 2017
Submission of responses:	5 October 2017
Re-start of the procedure:	2 November 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	10 November 2017
Comments:	20 November 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	23 November 2017
PRAC list of outstanding issues:	30 November 2017
Submission of responses:	28 December 2017
Re-start of the procedure:	11 January 2018
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	24 January 2018
Comments:	29 January 2018
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	01 February 2018
PRAC list of outstanding issues or PRAC recommendation to CHMP:	08 February 2018