17 May 2017 – rev. 7
EMA/PRAC/195601/2016

Timetable for the procedure

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

Gadolinium containing medicinal products

Procedure no: EMEA/H/A-31/1437

Optimark EMEA/H/A-31/1437/C/000745/0034

Procedural step:	**Date**:
Notification:	9 March 2016
Start of the procedure (PRAC):	March 2016 PRAC
List of questions:	17 March 2016
Submission of responses:	28 April 2016
Re-start of the procedure:	12 May 2016
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]:	25 May 2016
Comments:	30 May 2016
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	2 June 2016
PRAC list of outstanding issues:	June 2016 PRAC
Submission of MAH responses to list of outstanding issues:	10 August 2016

[1] Committee for Medicinal Products for Human Use

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Procedural step:	**Date**:
Re-start of the procedure:	1 September 2016
Ad-hoc expert group meeting:	5 September 2016
Joint rapporteur/co-rapporteur assessment report circulated to PRAC and to CHMP:	16 September 2016
Comments:	20 September 2016
Updated Joint rapporteur/co-rapporteur assessment report circulated to PRAC and to CHMP:	23 September 2016
PRAC list of outstanding issues:	29 September 2016 (October PRAC)
Submission of MAH responses to list of outstanding issues:	20 October 2016
Re-start of the procedure:	03 November 2016
Joint rapporteur/co-rapporteur assessment report circulated to PRAC and to CHMP:	16 November 2016
Comments:	21 November 2016
Updated Joint rapporteur/co-rapporteur assessment report circulated to PRAC and to CHMP:	24 November 2016
PRAC list of outstanding issues:	December 2016 PRAC
Submission of MAH responses to list of outstanding issues:	26 January 2017
Re-start of the procedure:	09 February 2017
Joint rapporteur/co-rapporteur assessment report circulated to PRAC and to CHMP:	22 February 2017
Comments:	28 February 2017
Updated Joint rapporteur/co-rapporteur assessment report circulated to PRAC and to CHMP:	02 March 2017
PRAC recommendation to CHMP	March 2017 PRAC
Re-examination - receipt of letters of intent from MAHs received by:	20 March 2017
Re-examination - Receipt of detailed grounds from MAHs received by:	15 May 2017
Re-examination - Start of re-examination procedure:	16 May 2017
Re-examination –rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	16 June 2017

Procedural step:	**Date**:
Ad-hoc expert group meeting:	19 June 2017
Re-examination – comments:	23 June 2017
Re-examination – Updated (Joint) rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CHMP:	28 June 2017
Re-examination - PRAC final recommendation:	July 2017 PRAC
CHMP opinion:	July 2017 CHMP