



28 September 2017
EMA/PRAC/460935/2016 Rev.2

Timetable for the procedure

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

Paracetamol modified and prolonged release tablets

Procedure no: EMEA/H/A-31/1445

Procedural step:	Date
Notification:	30 June 2016
Start of the procedure (PRAC):	July 2016 PRAC
List of questions:	07 July 2016
Submission of responses:	1 September 2016
Re-start of the procedure:	29 September 2016
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	5 October 2016
Comments:	17 October 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh	21 October 2016
PRAC list of outstanding issues:	27 October 2016 PRAC
Submission of responses:	26 January 2017
Re-start of the procedure:	9 February 2017

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	22 February 2017
Comments:	27 February 2017
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	2 March 2017
PRAC list of outstanding issues 2:	9 March 2017
Submission of responses:	6 June 2017
Re-start of the procedure:	8 June 2017
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	21 June 2017
Comments:	26 June 2017
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh	29 June 2017
PRAC list of outstanding issues 3:	6 July 2017
Submission of responses:	31 July 2017
Re-start of the procedure:	4 August 2017
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	21 August 2017
Comments:	25 August 2017
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	28 August 2017
PRAC recommendation:	1 September 2017
Re-examination - receipt of letters of intent from MAHs received:	18 and 21 September 2017
Re-examination - Receipt of detailed grounds from MAHs received by:	<i>By 06 November 2017 (tbc)</i>
Re-examination - Start of re-examination procedure:	<i>By 07 November (tbc)</i>
Re-examination –rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	<i>20 November 2017</i>
Ad-hoc expert group meeting:	<i>Date to be confirmed</i>

Procedural step:	Date
Re-examination – comments:	<i>22 November 2017</i>
Re-examination – Updated (Joint) rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CMDh:	<i>24 November 2017</i>
Re-examination - PRAC final recommendation:	<i>30 November 2017</i>
CMDh position:	<i>6-8 December 2017</i>