



25 July 2017  
EMA/PRAC/471536/2016 rev. 6

## Timetable for the procedure

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

Human and recombinant coagulation factor VIII containing medicinal products

Procedure no: EMEA/H/A-31/1448

Advate EMEA/H/A-31/1448/C/0520/0078, Elocta EMEA/H/A-31/1448/C/3964/0006  
Helixate Nexgen EMEA/H/A-31/1448/C/0276/0178, Iblis EMEA/H/A-31/1448/C/4147/0002  
Kogenate EMEA/H/A-31/1448/C/0275/0185, Kovaltry EMEA/H/A-31/1448/C/3825/0004  
Novoeight EMEA/H/A-31/1448/C/2719/0014, Nuwiq EMEA/H/A-31/1448/C/2813/0015, Refacto AF  
EMEA/H/A-31/1448/C/0232/0134, Voncento EMEA/H/A-31/1448/C/2493/0022

<b>Procedural step:</b>	<b>Date</b>
Notification:	06 July 2016
Start of the procedure (PRAC):	July 2016 PRAC
List of questions:	08 July 2016
Submission of responses:	10 September 2016
Re-start of the procedure:	29 September 2016
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP <sup>1</sup> :	14 October 2016
Comments:	19 October 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	21 October 2016
PRAC list of outstanding issues (LoOI):	October 2016 PRAC

<sup>1</sup> Committee for Medicinal Products for Human Use



<b>Procedural step:</b>	<b>Date</b>
Submission of responses:	26 January 2017
PRAC second LoOI:	06 February 2017
Submission of responses to the second LoOI:	09 February 2017
Re-start of the procedure:	09 February 2017
Ad-hoc expert group meeting:	22 February 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	22 February 2017
Comments:	27 February 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	02 March 2017
PRAC third LoOI:	March 2017 PRAC
Submission of responses to the third LoOI:	15 March 2017
Re-start of the procedure:	20 March 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	19 April 2017
Comments:	25 April 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	28 April 2017
PRAC recommendation to CHMP:	May 2017 PRAC
<b>Re-examination</b> - receipt of letter of intent from MAH:	26 May 2017
Re-examination - Receipt of detailed grounds from MAH:	05 July 2017
Re-examination - Start of re-examination procedure:	06 July 2017
Ad-hoc expert group meeting:	03 August 2017
Re-examination - Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CHMP:	14 August 2017
Re-examination - Comments:	21 August 2017
Re-examination - Updated (Joint) Assessment Report(s) circulated to PRAC and to CHMP:	24 August 2017

<b>Procedural step:</b>	<b>Date</b>
Re-examination - Oral explanation/PRAC final recommendation to CHMP:	September 2017 PRAC