EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 October 2013
EMA/PRAC/142799/2013 – Rev2

Timetable for the procedure

Procedure under Article 20(8) of Regulation (EC) No 726/2004, following procedural steps of Article 31 resulting from pharmacovigilance data

Procedure no: Kogenate Bayer EMEA/H/C/000275/A-20/0150
Helixate NexGen EMEA/H/C/000276/A-20/0143

Procedural step:	**Date:**
Notification:	04 March 2013
Start of the procedure (PRAC):	March 2013 PRAC
List of questions (LoQ):	07 March 2013
Submission of responses:	05 August 2013*
Re-start of the procedure:	12 August 2013
Rapporteur and co-rapporteur assessment report(s) circulated to PRAC and to CHMP[1]:	18 September 2013
Comments:	30 September 2013
Updated rapporteur and co-rapporteur assessment report(s) circulated to PRAC and to CHMP[1]	02 October 2013
PRAC list of outstanding issues (LoOI):	10 October 2013
Submission of responses:	04 November 2013
Joint Rapporteur/co-rapporteur assessment report circulated to PRAC and to CHMP:	21 November 2013

* Additional data are expected to be received by that date
[1] Committee for Medicinal Products for Human Use

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Procedural step:	**Date:**
Comments:	25 November 2013
Updated joint Rapporteur/co-rapporteur assessment report circulated to PRAC and to CHMP:	28 November 2013
PRAC recommendation/Oral Explanation:	December 2013 PRAC