



9 June 2017  
EMA/PRAC/787809/2016 rev.2

## Timetable for the procedure

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

Bovine lactose containing medicinal products for IV/IM use in acute allergy and/or anaphylactic shock

Procedure no: EMEA/H/A-31/1449

| <b>Procedural step:</b>   | <b>Date</b>        |
|---|--------------------|
| Notification:   | 21 November 2016   |
| Start of the procedure (PRAC):  | December 2016 PRAC |
| List of questions:  | 1 December 2016    |
| Submission of responses:  | 26 January 2017    |
| Re-start of the procedure:  | 9 February 2017    |
| Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh <sup>1</sup> : | 21 February 2017   |
| Comments:   | 27 February 2017   |
| Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh        | 2 March 2017       |
| PRAC list of outstanding issues:  | March 2017 PRAC    |
| Submission of responses:  | 28 April 2017      |
| Re-start of the procedure:  | 12 May 2017        |

<sup>1</sup> Coordination Group for Mutual Recognition & Decentralised Procedures - Human



| <b>Procedural step:</b>   | <b>Date</b>    |
|---|----------------|
| Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:         | 23 May 2017    |
| Comments:   | 30 May 2017    |
| Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh: | 02 June 2017   |
| PRAC 2 <sup>nd</sup> list of outstanding issues:  | June 2017 PRAC |
| Submission of responses:  | 14 June 2017   |
| Re-start of the procedure:  | 19 June 2017   |
| Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:         | 22 June 2017   |
| Comments:   | 27 June 2017   |
| Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh: | 29 June 2017   |
| PRAC 3 <sup>rd</sup> list of outstanding issues or PRAC recommendation to CMDh:             | July 2017 PRAC |