



7 July 2022
EMA/PRAC/2205/2022 rev3

Timetable for the procedure

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

Terlipressin-containing medicinal products indicated in the treatment of hepatorenal syndrome

Procedure no: EMEA/H/A-31/1514

Procedural step:	Date
Notification:	22 December 2021
Start of the procedure (PRAC):	January 2022 PRAC
List of questions:	13 January 2022
Submission of responses:	17 February 2022
Re-start of the procedure:	10 March 2022
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	18 March 2022
Comments:	25 March 2022
Updated rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	31 March 2022
PRAC list of outstanding issues:	07 April 2022
Submission of responses:	09 May 2022
Re-start of the procedure:	01 June 2022

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	09 June 2022
Ad-hoc Expert meeting (AHEG):	13 June 2022
Comments:	16 June 2022
Updated rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	22 June 2022
PRAC list of outstanding issues or PRAC recommendation to CMDh:	07 July 2022
Submission of responses:	11 August 2022
Re-start of the procedure:	01 September 2022
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	09 September 2022
Comments:	16 September 2022
Updated rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	22 September 2022
PRAC list of outstanding issues or PRAC recommendation to CMDh:	October 2022 PRAC (26 - 29 September)