



29 October 2020
EMA/PRAC/111338/2020 rev2

Timetable for the procedure

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

Ifosfamide-containing solutions

Procedure no: EMEA/H/A-31/1495

Procedural step:	Date
Notification:	28 February 2020
Start of the procedure (PRAC):	March 2020 PRAC
List of questions:	12 March 2020
Submission of responses:	12 May 2020
Re-start of the procedure:	11 June 2020
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	12 June 2020
Comments:	22 June 2020
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh:	26 June 2020
PRAC list of outstanding issues:	July, 2020 PRAC
Submission of responses:	3 September 2020

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Re-start of the procedure:	1 October 2020
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	6 October 2020
Comments:	13 October 2020
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	19 October 2020
PRAC list of outstanding issues:	November, 2020 PRAC (26-29 October)
Submission of responses:	14 January 2021
Re-start of the procedure:	11 February 2021
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	16 February 2021
Comments:	23 February 2021
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CMDh:	1 March 2021
PRAC list of outstanding issues or PRAC recommendation to CMDh:	March, 2021 PRAC