



14 February 2019
EMA/PRAC/199744/2018 Rev 2

Timetable for the procedure

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

Methotrexate containing medicinal products

Procedure no: EMEA/H/A-31/1463

Jylamvo EMEA/H/A-31/1463/C/3756/0002

Nordimet EMEA/H/A-31/1463/C/3983/0006

Procedural step:	Date
Notification:	22 March 2018
Start of the procedure (PRAC):	April 2018 PRAC
List of questions:	12 April 2018
Submission of MAH responses:	23 August 2018
Re-start of the procedure:	6 September 2018
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP ¹ :	19 September 2018
Comments:	25 September 2018
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	28 September 2018
PRAC list of outstanding issues	04 October 2018 PRAC

¹ Committee for Medicinal Products for Human Use



Procedural step:	Date
Submission of responses:	20 December 2018
Re-start of the procedure:	17 January 2019
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	21 January 2019
Comments:	01 February 2019
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	07 February 2019
PRAC list of outstanding issues:	14 February 2019
Submission of responses:	28 March 2019
Re-start of the procedure:	18 April 2019
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	25 April 2019
Comments:	03 May 2019
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CHMP:	10 May 2019
PRAC second list of outstanding issues or PRAC recommendation to CHMP:	May 2019 PRAC