



12 April 2018  
EMA/PRAC/199744/2018

## 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 <sup>1</sup> :	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 or PRAC recommendation to CHMP:	October 2018 PRAC

---

<sup>1</sup> Committee for Medicinal Products for Human Use

