



28 February 2019
EMA/CHMP/171344/2018 rev. 4

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

Omega-3 acid ethyl esters - containing medicinal products for oral in use in prevention after myocardial infarction

Procedure no: EMEA/H/A-31/1464

Procedural step:	Date
Notification:	15 March 2018
Start of the procedure (CHMP):	March 2018 CHMP
List of questions:	22 March 2018
Submission of responses:	17 May 2018
Re-start of the procedure:	31 May 2018
Rapporteur / co-rapporteur assessment reports circulated to CHMP:	13 June 2018
CHMP comments:	18 June 2018
Updated rapporteur/co-rapporteur assessment reports circulated to CHMP:	21 June 2018
CHMP list of outstanding issues:	June 2018 CHMP
Submission of responses:	6 September 2018
Re-start of the procedure:	20 September 2018



Procedural step:	Date
Rapporteur / co-rapporteur joint assessment report circulated to CHMP:	3 October 2018
SAG-CVS meeting:	10 October 2018
CHMP Comments:	8 October 2018
Updated rapporteur / co-rapporteur joint assessment report circulated to CHMP:	11 October 2018
2 nd List of Outstanding issues:	October 2018 CHMP
Submission of responses:	9 November 2018
Re-start of the procedure:	15 November 2018
Rapporteur / co-rapporteur joint assessment report circulated to CHMP:	30 November 2018
CHMP Comments:	5 December 2018
Updated rapporteur / co-rapporteur joint assessment report circulated to CHMP:	7 December 2018
CHMP opinion:	December 2018 CHMP
Re-examination - receipt of letters of intent from MAH:	19, 20, 21 December 2018, 2 January 2019
Re-examination - Receipt of detailed grounds from MAH:	16 February 2019
Re-examination - Start of re-examination procedure:	17 February 2019
Re-examination - Rapporteur/co-rapporteur assessment reports circulated to CHMP:	12 March 2019
Re-examination – CHMP Comments:	15 March 2019
Re-examination – SAG-CVS meeting:	19 March 2019
Re-examination - Rapporteur / co-rapporteur joint assessment report:	20 March 2019
Re-examination - CHMP final opinion:	March 2019 CHMP