



31 July 2020
EMA/CHMP/506572/2019 Rev. 3

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

Ranitidine-containing medicinal products

Procedure no: EMEA/H/A-31/1491

Procedural step:	Date
Notification:	12 September 2019
Start of the procedure (CHMP):	September, 2019 CHMP
List of questions:	19 September 2019
Submission of responses:	24 October 2019
Re-start of the procedure:	14 November 2019
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	22 November 2019
Comments:	29 November 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	05 December 2019
CHMP list of outstanding issues:	December 2019 CHMP
Submission of responses:	09 January 2020
Re-start of the procedure:	30 January 2020
Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	07 February 2020

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

An agency of the European Union



Procedural step:	Date
Comments:	14 February 2020
Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	20 February 2020
CHMP list of outstanding issues:	February 2020 CHMP
Submission of responses:	9 March 2020
Re-start of the procedure:	16 March 2020
Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	20 March 2020
Comments:	15 April 2020
Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	23 April 2020
CHMP opinion:	April 2020
Re-examination - receipt of letter of intent from MAH:	3 June 2020
Re-examination - receipt of detailed grounds from MAH:	29 July 2020
Re-examination - Start of re-examination procedure:	30 July 2020
Re-examination - Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	28 August 2020
Re-examination – Comments:	04 September 2020
Re-examination - Joint updated assessment report circulated to CHMP:	10 September 2020
Re-examination - Oral explanation/CHMP final opinion:	September, 2020 CHMP