



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

19 July 2022
EMA/CHMP/25665/2022 Rev. 1

Timetable for the procedure - re-examination

Referral under article 31 of Directive 2001/83/EC

Medicinal products which have been authorised or are pending approval based on studies conducted by Synchron Research Services, a contract research organisation (CRO) located in Ahmedabad, Gujarat, India

Procedure no: EMEA/H/A-31/1515

Procedural step:	Date
Notifications:	11 January 2022
Start of the procedure (CHMP):	January, 2022 CHMP
List of questions:	27 January 2022
Submission of responses:	04 March 2022
Re-start of the procedure:	25 March 2022
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	28 April 2022
Comments:	06 May 2022
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	12 May 2022
CHMP opinion:	19 May 2022
Re-examination - receipt of letter of intent from MAH:	23 May 2022
Re-examination - receipt of detailed grounds from MAH:	18 July 2022

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
Re-examination - Start of re-examination procedure:	19 July 2022
Re-examination - Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	18 August 2022
Re-examination – Comments:	29 August 2022
Re-examination - Joint updated assessment report circulated to CHMP:	2 September 2022
Re-examination - Oral explanation/CHMP final opinion:	September, 2022 CHMP