



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

14 February 2024  
EMA/CHMP/304425/2023 Rev. 1

## Timetable for the procedure

### Referral under article 31 of Directive 2001/83/EC

Medicinal products which have been authorised or are pending approval based on studies conducted by Synapse Labs Pvt. Ltd, a contract research organisation (CRO) located in Kharadi, Pune, India.

Procedure no: EMEA/H/A-31/1529

<b>Procedural step:</b>	<b>Date</b>
Notification:	27 June 2023
Start of the procedure (CHMP):	July, 2023 CHMP
List of questions:	20 July 2023
Submission of responses:	15 September 2023
Re-start of the procedure:	16 October 2023
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	24 November 2023
Comments:	01 December 2023
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	07 December 2023
CHMP opinion:	December, 2023 CHMP
Re-examination - receipt of letters of intent from MAH:	19, 20, 21, 22 December 2023
Re-examination - Start of re-examination procedure:	14 February 2024
Re-examination - Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	07 March 2024

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<b>Procedural step:</b>	<b>Date</b>
Re-examination – Comments:	12 March 2024
Re-examination - Joint updated assessment report circulated to CHMP:	14 March 2024
Re-examination - Oral explanation/CHMP final opinion:	March, 2024 CHMP