10 June 2021
EMA/PRAC/104559/2021 Rev. 1

# Timetable for the procedure

Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data

ZYNTEGLO

Procedure number: EMEA/H/A-20/1504/C/003691/0023

| **Procedural step*:** | **Date** |
|---|---|
| Notification: | 18 February 2021 |
| Start of the procedure (PRAC): | 11 March 2021 |
| List of questions: | 11 March 2021 |
| Submission of responses: | 22 April 2021 |
| Re-start of the procedure: | 23 April 2021 |
| Rapporteur/co-rapporteur assessment reports circulated to PRAC: | 21 May 2021 |
| Comments: | 28 May 2021 |
| Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC: | 3 June 2021 |
| PRAC list of outstanding issues: | 10 June 2021 |
| Submission of responses: | 16 June 2021 |
| Re-start of the procedure: | 21 June 2021 |
| Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC: | 25 June 2021 |



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| **Procedural step*:** | **Date** |
|---|---|
| Comments: | 30 June 2021 |
| Updated rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC: | 2 July 2021 |
| PRAC list of outstanding issues / PRAC recommendation to CAT[1] and CHMP[2]: | July 2021 PRAC |

*PRAC will be working closely with experts from the CAT



[1] Committee for Advanced Therapies
[2] Committee for Medicinal Products for Human Use