



20 January 2021
EMA/823130/2015 Rev.2
Human Medicines Division

The timetables in this document may be subject to revision

Annual re-assessment*

[Assessment of initial submission \(90-day timetable\)](#)

[Assessment of responses to Request for Supplementary Information \(30-day timetable after clock-stop for responses\)](#)

[Assessment of responses to Request for Supplementary Information \(30-day timetable after immediate responses\)](#)

(*) This type of assessment applies to marketing authorisations granted under exceptional circumstances according to Article 22 and its Annex I, Part II.6 of Directive 2001/83/EC and Article 14(8) of Regulation (EC) No 726/2004.

Assessment of initial submission

90-day timetable

| | Deadline for Submission (*) | Start date (^) | CHMP and PRAC Rapporteur Joint AR | Comments from PRAC and CHMP (**) | Updated CHMP and PRAC Rapporteur Joint AR (***) | PRAC outcome | Request for Supplementary Information (RSI) or Opinion |
|-----|-----------------------------|----------------|-----------------------------------|----------------------------------|---|--------------|--|
| A1 | 15/01/2020 | 01/02/2020 | 31/03/2020 | 06/04/2020 | 08/04/2020 | 17/04/2020 | 30/04/2020 |
| A2 | 12/02/2020 | 29/02/2020 | 28/04/2020 | 04/05/2020 | 07/05/2020 | 14/05/2020 | 28/05/2020 |
| A3 | 11/03/2020 | 28/03/2020 | 26/05/2020 | 02/06/2020 | 04/06/2020 | 11/06/2020 | 25/06/2020 |
| A4 | 03/04/2020 | 25/04/2020 | 23/06/2020 | 29/06/2020 | 02/07/2020 | 09/07/2020 | 23/07/2020 |
| A5 | | | | | | | |
| A6 | 03/06/2020 | 20/06/2020 | 18/08/2020 | 24/08/2020 | 27/08/2020 | 04/09/2020 | 17/09/2020 |
| A7 | 01/07/2020 | 18/07/2020 | 15/09/2020 | 21/09/2020 | 24/09/2020 | 01/10/2020 | 15/10/2020 |
| A8 | 29/07/2020 | 15/08/2020 | 13/10/2020 | 19/10/2020 | 22/10/2020 | 29/10/2020 | 12/11/2020 |
| A9 | 26/08/2020 | 12/09/2020 | 10/11/2020 | 16/11/2020 | 19/11/2020 | 26/11/2020 | 10/12/2020 |
| A10 | 14/10/2020 | 31/10/2020 | 22/12/2020 | 04/01/2021 | 07/01/2021 | 14/01/2021 | 28/01/2021 |
| A11 | 11/11/2020 | 28/11/2020 | 26/01/2021 | 01/02/2021 | 04/02/2021 | 11/02/2021 | 25/02/2021 |
| A12 | 25/11/2020 | 26/12/2020 | 23/02/2021 | 01/03/2021 | 04/03/2021 | 11/03/2021 | 25/03/2021 |
| A13 | 06/01/2021 | 23/01/2021 | 23/03/2021 | 29/03/2021 | 31/03/2021 | 09/04/2021 | 22/04/2021 |
| A14 | 03/02/2021 | 20/02/2021 | 20/04/2021 | 26/04/2021 | 29/04/2021 | 06/05/2021 | 20/05/2021 |
| A15 | 10/03/2021 | 27/03/2021 | 25/05/2021 | 31/05/2021 | 03/06/2021 | 10/06/2021 | 24/06/2021 |
| A16 | 07/04/2021 | 24/04/2021 | 22/06/2021 | 28/06/2021 | 01/07/2021 | 08/07/2021 | 22/07/2021 |
| A17 | | | | | | | |
| A18 | 02/06/2021 | 19/06/2021 | 17/08/2021 | 23/08/2021 | 26/08/2021 | 03/09/2021 | 16/09/2021 |
| A19 | 30/06/2021 | 17/07/2021 | 14/09/2021 | 20/09/2021 | 23/09/2021 | 30/09/2021 | 14/10/2021 |
| A20 | 28/07/2021 | 14/08/2021 | 12/10/2021 | 18/10/2021 | 21/10/2021 | 28/10/2021 | 11/11/2021 |
| A21 | 01/09/2021 | 18/09/2021 | 16/11/2021 | 22/11/2021 | 25/11/2021 | 02/12/2021 | 16/12/2021 |
| A22 | 13/10/2021 | 30/10/2021 | 21/12/2021 | 03/01/2022 | 06/01/2022 | 13/01/2022 | 27/01/2022 |
| A23 | 10/11/2021 | 27/11/2021 | 25/01/2022 | 31/01/2022 | 03/02/2022 | 10/02/2022 | 24/02/2022 |
| A24 | 01/12/2021 | 25/12/2021 | 22/02/2022 | 28/02/2022 | 03/03/2022 | 10/03/2022 | 24/03/2022 |
| A25 | 06/01/2022 | 23/01/2022 | 22/03/2022 | 28/03/2022 | 31/03/2022 | 07/04/2022 | 22/04/2022 |
| A26 | 02/02/2022 | 19/02/2022 | 19/04/2022 | 25/04/2022 | 28/04/2022 | 05/05/2022 | 19/05/2022 |
| A27 | 09/03/2022 | 26/03/2022 | 24/05/2022 | 30/05/2022 | 02/06/2022 | 10/06/2022 | 23/06/2022 |
| A28 | 06/04/2022 | 23/04/2022 | 21/06/2022 | 27/06/2022 | 30/06/2022 | 07/07/2022 | 21/07/2022 |
| A29 | | | | | | | |
| A30 | 01/06/2022 | 18/06/2022 | 16/08/2022 | 22/08/2022 | 25/08/2022 | 01/09/2022 | 15/09/2022 |
| A31 | 29/06/2022 | 16/07/2022 | 13/09/2022 | 19/09/2022 | 22/09/2022 | 29/09/2022 | 13/10/2022 |
| A32 | 27/07/2022 | 13/08/2022 | 11/10/2022 | 17/10/2022 | 20/10/2022 | 27/10/2022 | 10/11/2022 |
| A33 | 31/08/2022 | 17/09/2022 | 15/11/2022 | 21/11/2022 | 24/11/2022 | 01/12/2022 | 15/12/2022 |
| A34 | 12/10/2022 | 29/10/2022 | 20/12/2022 | 03/01/2023 | 05/01/2023 | 12/01/2023 | 26/01/2023 |
| A35 | 09/11/2022 | 26/11/2022 | 24/01/2023 | 30/01/2023 | 02/02/2023 | 09/02/2023 | 23/02/2023 |
| A36 | 30/11/2022 | 31/12/2022 | 28/02/2023 | 06/03/2023 | 09/03/2023 | 16/03/2023 | 30/03/2023 |
| A37 | 10/01/2023 | 27/01/2023 | 28/03/2023 | 03/04/2023 | 05/04/2023 | 14/04/2023 | 26/04/2023 |
| A38 | 08/02/2023 | 25/02/2023 | 25/04/2023 | 02/05/2023 | 04/05/2023 | 12/05/2023 | 25/05/2023 |
| A39 | 08/03/2023 | 25/03/2023 | 23/05/2023 | 26/05/2023 | 01/06/2023 | 08/06/2023 | 22/06/2023 |

| | Deadline for Submission (*) | Start date (^) | CHMP and PRAC Rapporteur Joint AR | Comments from PRAC and CHMP (**) | Updated CHMP and PRAC Rapporteur Joint AR (***) | PRAC outcome | Request for Supplementary Information (RSI) or Opinion |
|-----|-----------------------------|----------------|-----------------------------------|----------------------------------|---|--------------|--|
| A40 | 05/04/2023 | 22/04/2023 | 20/06/2023 | 26/06/2023 | 29/06/2023 | 06/07/2023 | 20/07/2023 |
| A41 | | | | | | | |
| A42 | 31/05/2023 | 17/06/2023 | 16/08/2023 | 21/08/2023 | 24/08/2023 | 31/08/2023 | 14/09/2023 |
| A43 | 28/06/2023 | 15/07/2023 | 12/09/2023 | 18/09/2023 | 21/09/2023 | 28/09/2023 | 12/10/2023 |
| A44 | 26/07/2023 | 12/08/2023 | 10/10/2023 | 16/10/2023 | 19/10/2023 | 26/10/2023 | 09/11/2023 |
| A45 | 30/08/2023 | 16/09/2023 | 14/11/2023 | 20/11/2023 | 23/11/2023 | 30/11/2023 | 14/12/2023 |
| A46 | 11/10/2023 | 28/10/2023 | 19/12/2023 | 03/01/2024 | 05/01/2024 | 11/01/2024 | 25/01/2024 |
| A47 | 08/11/2023 | 25/11/2023 | 23/01/2024 | 29/01/2024 | 01/02/2024 | 08/02/2024 | 22/02/2024 |
| A48 | 29/11/2023 | 23/12/2023 | 20/02/2024 | 26/02/2024 | 29/02/2024 | 07/03/2024 | 21/03/2024 |
| A49 | 10/01/2024 | 27/01/2024 | 26/03/2024 | 02/04/2024 | 04/04/2024 | 11/04/2024 | 25/04/2024 |
| A50 | 14/02/2024 | 02/03/2024 | 30/04/2024 | 06/05/2024 | 08/05/2024 | 16/05/2024 | 30/05/2024 |
| A51 | 13/03/2024 | 30/03/2024 | 28/05/2024 | 03/06/2024 | 06/06/2024 | 13/06/2024 | 27/06/2024 |
| A52 | 10/04/2024 | 27/04/2024 | 25/06/2024 | 01/07/2024 | 04/07/2024 | 11/07/2024 | 25/07/2024 |
| A53 | | | | | | | |
| A54 | 05/06/2024 | 22/06/2024 | 20/08/2024 | 26/08/2024 | 29/08/2024 | 05/09/2024 | 19/09/2024 |
| A55 | 03/07/2024 | 20/07/2024 | 17/09/2024 | 23/09/2024 | 26/09/2024 | 03/10/2024 | 17/10/2024 |
| A56 | 31/07/2024 | 17/08/2024 | 15/10/2024 | 21/10/2024 | 24/10/2024 | 31/10/2024 | 14/11/2024 |
| A57 | 28/08/2024 | 14/09/2024 | 12/11/2024 | 18/11/2024 | 21/11/2024 | 28/11/2024 | 12/12/2024 |

(*) Annual re-assessment applications should be submitted as close as possible to the anniversary date of the Commission Decision granting the marketing authorisation. Flexibility in the submission date could, however, be envisaged in order to synchronise the annual re-assessment submission with the submission of data from the Specific Obligations. Annual re-assessment application submissions could be adjusted within a maximum of +/- 2 months in such cases.

The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and needs to be re-despatched.

(^) The validation period between submission date and start date is usually sixteen calendar days.

(**) Comments from PRAC and CHMP members are not made available to Marketing Authorisation Holders.

(***) An updated AR is optional and dependent on the comments received from committee (PRAC, CHMP) members which create the need for the update.

Assessment of responses to Request for Supplementary Information 30-day timetable after clock-stop for responses

| | Deadline for Submission (*) | Re-start date | CHMP and PRAC Rapporteur Joint AR | Comments from PRAC and CHMP (**) | Updated CHMP and PRAC Rapporteur Joint AR (***) | PRAC outcome | Opinion |
|-----|-----------------------------|---------------|-----------------------------------|----------------------------------|---|--------------|------------|
| B1 | 28/01/2020 | 29/01/2020 | 03/02/2020 | 05/02/2020 | 06/02/2020 | 13/02/2020 | 27/02/2020 |
| B2 | 25/02/2020 | 26/02/2020 | 02/03/2020 | 04/03/2020 | 05/03/2020 | 12/03/2020 | 26/03/2020 |
| B3 | 31/03/2020 | 01/04/2020 | 06/04/2020 | 07/04/2020 | 08/04/2020 | 17/04/2020 | 30/04/2020 |
| B4 | 28/04/2020 | 29/04/2020 | 04/05/2020 | 06/05/2020 | 07/05/2020 | 14/05/2020 | 28/05/2020 |
| B5 | 26/05/2020 | 27/05/2020 | 29/05/2020 | 03/06/2020 | 04/06/2020 | 11/06/2020 | 25/06/2020 |
| B6 | 23/06/2020 | 24/06/2020 | 29/06/2020 | 01/07/2020 | 02/07/2020 | 09/07/2020 | 23/07/2020 |
| B7 | | | | | | | |
| B8 | 18/08/2020 | 19/08/2020 | 24/08/2020 | 26/08/2020 | 27/08/2020 | 04/09/2020 | 17/09/2020 |
| B9 | 15/09/2020 | 16/09/2020 | 21/09/2020 | 23/09/2020 | 24/09/2020 | 01/10/2020 | 15/10/2020 |
| B10 | 13/10/2020 | 14/10/2020 | 19/10/2020 | 21/10/2020 | 22/10/2020 | 29/10/2020 | 12/11/2020 |
| B11 | 10/11/2020 | 11/11/2020 | 16/11/2020 | 18/11/2020 | 19/11/2020 | 26/11/2020 | 10/12/2020 |
| B12 | 23/12/2020 | 30/12/2020 | 04/01/2021 | 06/01/2021 | 07/01/2021 | 14/01/2021 | 28/01/2021 |
| B13 | 26/01/2021 | 27/01/2021 | 01/02/2021 | 03/02/2021 | 04/02/2021 | 11/02/2021 | 25/02/2021 |
| B14 | 23/02/2021 | 24/02/2021 | 01/03/2021 | 03/03/2021 | 04/03/2021 | 11/03/2021 | 25/03/2021 |
| B15 | 23/03/2021 | 24/03/2021 | 29/03/2021 | 30/03/2021 | 31/03/2021 | 09/04/2021 | 22/04/2021 |
| B16 | 20/04/2021 | 21/04/2021 | 26/04/2021 | 28/04/2021 | 29/04/2021 | 06/05/2021 | 20/05/2021 |
| B17 | 25/05/2021 | 26/05/2021 | 31/05/2021 | 02/06/2021 | 03/06/2021 | 10/06/2021 | 24/06/2021 |
| B18 | 22/06/2021 | 23/06/2021 | 28/06/2021 | 30/06/2021 | 01/07/2021 | 08/07/2021 | 22/07/2021 |
| B19 | | | | | | | |
| B20 | 17/08/2021 | 18/08/2021 | 23/08/2021 | 25/08/2021 | 26/08/2021 | 03/09/2021 | 16/09/2021 |
| B21 | 14/09/2021 | 15/09/2021 | 20/09/2021 | 22/09/2021 | 23/09/2021 | 30/09/2021 | 14/10/2021 |
| B22 | 12/10/2021 | 13/10/2021 | 18/10/2021 | 20/10/2021 | 21/10/2021 | 28/10/2021 | 11/11/2021 |
| B23 | 16/11/2021 | 17/11/2021 | 22/11/2021 | 24/11/2021 | 25/11/2021 | 02/12/2021 | 16/12/2021 |
| B24 | 22/12/2021 | 29/12/2021 | 03/01/2022 | 05/01/2022 | 06/01/2022 | 13/01/2022 | 27/01/2022 |
| B25 | 25/01/2022 | 26/01/2022 | 31/01/2022 | 02/02/2022 | 03/02/2022 | 10/02/2022 | 24/02/2022 |
| B26 | 22/02/2022 | 23/02/2022 | 28/02/2022 | 02/03/2022 | 03/03/2022 | 10/03/2022 | 24/03/2022 |
| B27 | 23/03/2022 | 24/03/2022 | 28/03/2022 | 30/03/2022 | 31/03/2022 | 07/04/2022 | 22/04/2022 |
| B28 | 19/04/2022 | 20/04/2022 | 25/04/2022 | 26/04/2022 | 28/04/2022 | 05/05/2022 | 19/05/2022 |
| B29 | 24/05/2022 | 25/05/2022 | 30/05/2022 | 01/06/2022 | 02/06/2022 | 10/06/2022 | 23/06/2022 |
| B30 | 21/06/2022 | 22/06/2022 | 27/06/2022 | 29/06/2022 | 30/06/2022 | 07/07/2022 | 21/07/2022 |
| B31 | | | | | | | |
| B32 | 16/08/2022 | 17/08/2022 | 22/08/2022 | 24/08/2022 | 25/08/2022 | 01/09/2022 | 15/09/2022 |
| B33 | 13/09/2022 | 14/09/2022 | 19/09/2022 | 21/09/2022 | 22/09/2022 | 29/09/2022 | 13/10/2022 |
| B34 | 11/10/2022 | 12/10/2022 | 17/10/2022 | 19/10/2022 | 20/10/2022 | 27/10/2022 | 10/11/2022 |
| B35 | 15/11/2022 | 16/11/2022 | 21/11/2022 | 23/11/2022 | 24/11/2022 | 01/12/2022 | 15/12/2022 |
| B36 | 22/12/2022 | 28/12/2022 | 03/01/2023 | 04/01/2023 | 05/01/2023 | 12/01/2023 | 26/01/2023 |
| B37 | 24/01/2023 | 25/01/2023 | 30/01/2023 | 01/02/2023 | 02/02/2023 | 09/02/2023 | 23/02/2023 |
| B38 | 28/02/2023 | 01/03/2023 | 06/03/2023 | 08/03/2023 | 09/03/2023 | 16/03/2023 | 30/03/2023 |
| B39 | 27/03/2023 | 28/03/2023 | 03/04/2023 | 04/04/2023 | 05/04/2023 | 14/04/2023 | 26/04/2023 |

| | Deadline for Submission (*) | Re-start date | CHMP and PRAC Rapporteur Joint AR | Comments from PRAC and CHMP (**) | Updated CHMP and PRAC Rapporteur Joint AR (***) | PRAC outcome | Opinion |
|-----|-----------------------------|---------------|-----------------------------------|----------------------------------|---|--------------|------------|
| B40 | 25/04/2023 | 26/04/2023 | 02/05/2023 | 03/05/2023 | 04/05/2023 | 12/05/2023 | 25/05/2023 |
| B41 | 23/05/2023 | 24/05/2023 | 30/05/2023 | 31/05/2023 | 01/06/2023 | 08/06/2023 | 22/06/2023 |
| B42 | 20/06/2023 | 21/06/2023 | 26/06/2023 | 28/06/2023 | 29/06/2023 | 06/07/2023 | 20/07/2023 |
| B43 | | | | | | | |
| B44 | 14/08/2023 | 16/08/2023 | 21/08/2023 | 23/08/2023 | 24/08/2023 | 31/08/2023 | 14/09/2023 |
| B45 | 12/09/2023 | 13/09/2023 | 18/09/2023 | 20/09/2023 | 21/09/2023 | 28/09/2023 | 12/10/2023 |
| B46 | 10/10/2023 | 11/10/2023 | 16/10/2023 | 18/10/2023 | 19/10/2023 | 26/10/2023 | 09/11/2023 |
| B47 | 14/11/2023 | 15/11/2023 | 20/11/2023 | 22/11/2023 | 23/11/2023 | 30/11/2023 | 14/12/2023 |
| B48 | 21/12/2023 | 27/12/2023 | 03/01/2024 | 04/01/2024 | 05/01/2024 | 11/01/2024 | 25/01/2024 |
| B49 | 23/01/2024 | 24/01/2024 | 29/01/2024 | 31/01/2024 | 01/02/2024 | 08/02/2024 | 22/02/2024 |
| B50 | 20/02/2024 | 21/02/2024 | 26/02/2024 | 28/02/2024 | 29/02/2024 | 07/03/2024 | 21/03/2024 |
| B51 | 26/03/2024 | 27/03/2024 | 02/04/2024 | 03/04/2024 | 04/04/2024 | 11/04/2024 | 25/04/2024 |
| B52 | 30/04/2024 | 01/05/2024 | 06/05/2024 | 07/05/2024 | 08/05/2024 | 16/05/2024 | 30/05/2024 |
| B53 | 28/05/2024 | 29/05/2024 | 03/06/2024 | 05/06/2024 | 06/06/2024 | 13/06/2024 | 27/06/2024 |
| B54 | 25/06/2024 | 26/06/2024 | 01/07/2024 | 03/07/2024 | 04/07/2024 | 11/07/2024 | 25/07/2024 |
| B55 | | | | | | | |
| B56 | 20/08/2024 | 21/08/2024 | 26/08/2024 | 28/08/2024 | 29/08/2024 | 05/09/2024 | 19/09/2024 |
| B57 | 17/09/2024 | 18/09/2024 | 23/09/2024 | 25/09/2024 | 26/09/2024 | 03/10/2024 | 17/10/2024 |
| B58 | 15/10/2024 | 16/10/2024 | 21/10/2024 | 23/10/2024 | 24/10/2024 | 31/10/2024 | 14/11/2024 |
| B59 | 12/11/2024 | 13/11/2024 | 18/11/2024 | 20/11/2024 | 21/11/2024 | 28/11/2024 | 12/12/2024 |

(*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(**) Comments from PRAC and CHMP members are not made available to Marketing Authorisation Holders.

(***) An updated AR is optional and dependent on the comments received from committee (PRAC, CHMP) members which create the need for the update.

Assessment of responses to Request for Supplementary Information 30-day timetable after immediate responses¹

| | Deadline for Submission (*) | Re-start date | CHMP and PRAC Rapporteur Joint AR | PRAC outcome | Comments from CHMP (**) | Updated CHMP and PRAC Rapporteur Joint AR (***) | Opinion |
|-----|-----------------------------|---------------|-----------------------------------|--------------|-------------------------|---|------------|
| C1 | 04/02/2020 | 05/02/2020 | 12/02/2020 | 13/02/2020 | 17/02/2020 | 20/02/2020 | 27/02/2020 |
| C2 | 03/03/2020 | 04/03/2020 | 11/03/2020 | 12/03/2020 | 16/03/2020 | 19/03/2020 | 26/03/2020 |
| C3 | 02/04/2020 | 03/04/2020 | 15/04/2020 | 17/04/2020 | 20/04/2020 | 23/04/2020 | 30/04/2020 |
| C4 | 05/05/2020 | 06/05/2020 | 13/05/2020 | 14/05/2020 | 18/05/2020 | 20/05/2020 | 28/05/2020 |
| C5 | 02/06/2020 | 03/06/2020 | 10/06/2020 | 11/06/2020 | 15/06/2020 | 18/06/2020 | 25/06/2020 |
| C6 | 30/06/2020 | 01/07/2020 | 08/07/2020 | 09/07/2020 | 13/07/2020 | 16/07/2020 | 23/07/2020 |
| C7 | | | | | | | |
| C8 | 18/08/2020 | 19/08/2020 | 02/09/2020 | 04/09/2020 | 07/09/2020 | 10/09/2020 | 17/09/2020 |
| C9 | 22/09/2020 | 23/09/2020 | 30/09/2020 | 01/10/2020 | 05/10/2020 | 08/10/2020 | 15/10/2020 |
| C10 | 20/10/2020 | 21/10/2020 | 28/10/2020 | 29/10/2020 | 03/11/2020 | 05/11/2020 | 12/11/2020 |
| C11 | 17/11/2020 | 18/11/2020 | 25/11/2020 | 26/11/2020 | 30/11/2020 | 03/12/2020 | 10/12/2020 |
| C12 | 23/12/2020 | 30/12/2020 | 13/01/2021 | 14/01/2021 | 18/01/2021 | 21/01/2021 | 28/01/2021 |
| C13 | 02/02/2021 | 03/02/2021 | 10/02/2021 | 11/02/2021 | 15/02/2021 | 18/02/2021 | 25/02/2021 |
| C14 | 02/03/2021 | 03/03/2021 | 10/03/2021 | 11/03/2021 | 15/03/2021 | 18/03/2021 | 25/03/2021 |
| C15 | 30/03/2021 | 31/03/2021 | 07/04/2021 | 09/04/2021 | 12/04/2021 | 15/04/2021 | 22/04/2021 |
| C16 | 27/04/2021 | 28/04/2021 | 05/05/2021 | 06/05/2021 | 10/05/2021 | 12/05/2021 | 20/05/2021 |
| C17 | 27/05/2021 | 28/05/2021 | 09/06/2021 | 10/06/2021 | 14/06/2021 | 17/06/2021 | 24/06/2021 |
| C18 | 29/06/2021 | 30/06/2021 | 07/07/2021 | 08/07/2021 | 12/07/2021 | 15/07/2021 | 22/07/2021 |
| C19 | | | | | | | |
| C20 | 17/08/2021 | 18/08/2021 | 01/09/2021 | 03/09/2021 | 06/09/2021 | 09/09/2021 | 16/09/2021 |
| C21 | 21/09/2021 | 22/09/2021 | 29/09/2021 | 30/09/2021 | 04/10/2021 | 07/10/2021 | 14/10/2021 |
| C22 | 19/10/2021 | 20/10/2021 | 27/10/2021 | 28/10/2021 | 03/11/2021 | 05/11/2021 | 11/11/2021 |
| C23 | 18/11/2021 | 19/11/2021 | 01/12/2021 | 02/12/2021 | 06/12/2021 | 09/12/2021 | 16/12/2021 |
| C24 | 22/12/2021 | 29/12/2021 | 12/01/2022 | 13/01/2022 | 17/01/2022 | 20/01/2022 | 27/01/2022 |
| C25 | 01/02/2022 | 02/02/2022 | 09/02/2022 | 10/02/2022 | 14/02/2022 | 17/02/2022 | 24/02/2022 |
| C26 | 01/03/2022 | 02/03/2022 | 09/03/2022 | 10/03/2022 | 14/03/2022 | 17/03/2022 | 24/03/2022 |
| C27 | 30/03/2022 | 31/03/2022 | 06/04/2022 | 07/04/2022 | 11/04/2022 | 13/04/2022 | 22/04/2022 |
| C28 | 26/04/2022 | 27/04/2022 | 04/05/2022 | 05/05/2022 | 10/05/2022 | 12/05/2022 | 19/05/2022 |
| C29 | 25/05/2022 | 27/05/2022 | 08/06/2022 | 10/06/2022 | 13/06/2022 | 16/06/2022 | 23/06/2022 |
| C30 | 28/06/2022 | 29/06/2022 | 06/07/2022 | 07/07/2022 | 11/07/2022 | 14/07/2022 | 21/07/2022 |
| C31 | | | | | | | |
| C32 | 16/08/2022 | 17/08/2022 | 31/08/2022 | 01/09/2022 | 05/09/2022 | 08/09/2022 | 15/09/2022 |
| C33 | 20/09/2022 | 21/09/2022 | 28/09/2022 | 29/09/2022 | 03/10/2022 | 06/10/2022 | 13/10/2022 |
| C34 | 18/10/2022 | 19/10/2022 | 26/10/2022 | 27/10/2022 | 28/10/2022 | 03/11/2022 | 10/11/2022 |
| C35 | 16/11/2022 | 18/11/2022 | 30/11/2022 | 01/12/2022 | 05/12/2022 | 08/12/2022 | 15/12/2022 |
| C36 | 22/12/2022 | 28/12/2022 | 11/01/2023 | 12/01/2023 | 16/01/2023 | 19/01/2023 | 26/01/2023 |
| C37 | 31/01/2023 | 01/02/2023 | 08/02/2023 | 09/02/2023 | 13/02/2023 | 16/02/2023 | 23/02/2023 |
| C38 | 28/02/2023 | 01/03/2023 | 15/03/2023 | 16/03/2023 | 20/03/2023 | 23/03/2023 | 30/03/2023 |
| C39 | 03/04/2023 | 04/04/2023 | 11/04/2023 | 14/04/2023 | 17/04/2023 | 20/04/2023 | 26/04/2023 |

| | Deadline for Submission (*) | Re-start date | CHMP and PRAC Rapporteur Joint AR | PRAC outcome | Comments from CHMP (**) | Updated CHMP and PRAC Rapporteur Joint AR (***) | Opinion |
|-----|-----------------------------|---------------|-----------------------------------|--------------|-------------------------|---|------------|
| C40 | 02/05/2023 | 03/05/2023 | 10/05/2023 | 12/05/2023 | 15/05/2023 | 17/05/2023 | 25/05/2023 |
| C41 | 30/05/2023 | 31/05/2023 | 07/06/2023 | 08/06/2023 | 12/06/2023 | 15/06/2023 | 22/06/2023 |
| C42 | 27/06/2023 | 28/06/2023 | 05/07/2023 | 06/07/2023 | 10/07/2023 | 13/07/2023 | 20/07/2023 |
| C43 | | | | | | | |
| C44 | 14/08/2023 | 16/08/2023 | 30/08/2023 | 31/08/2023 | 04/09/2023 | 07/09/2023 | 14/09/2023 |
| C45 | 19/09/2023 | 20/09/2023 | 27/09/2023 | 28/09/2023 | 02/10/2023 | 05/10/2023 | 12/10/2023 |
| C46 | 17/10/2023 | 18/10/2023 | 25/10/2023 | 26/10/2023 | 30/10/2023 | 31/10/2023 | 09/11/2023 |
| C47 | 16/11/2023 | 17/11/2023 | 29/11/2023 | 30/11/2023 | 04/12/2023 | 07/12/2023 | 14/12/2023 |
| C48 | 21/12/2023 | 27/12/2023 | 10/01/2024 | 11/01/2024 | 15/01/2024 | 18/01/2024 | 25/01/2024 |
| C49 | 30/01/2024 | 31/01/2024 | 07/02/2024 | 08/02/2024 | 12/02/2024 | 15/02/2024 | 22/02/2024 |
| C50 | 27/02/2024 | 28/02/2024 | 06/03/2024 | 07/03/2024 | 11/03/2024 | 14/03/2024 | 21/03/2024 |
| C51 | 27/03/2024 | 29/03/2024 | 10/04/2024 | 11/04/2024 | 15/04/2024 | 18/04/2024 | 25/04/2024 |
| C52 | 02/05/2024 | 03/05/2024 | 15/05/2024 | 16/05/2024 | 21/05/2024 | 23/05/2024 | 30/05/2024 |
| C53 | 04/06/2024 | 05/06/2024 | 12/06/2024 | 13/06/2024 | 17/06/2024 | 20/06/2024 | 27/06/2024 |
| C54 | 02/07/2024 | 03/07/2024 | 10/07/2024 | 11/07/2024 | 15/07/2024 | 18/07/2024 | 25/07/2024 |
| C55 | | | | | | | |
| C56 | 20/08/2024 | 21/08/2024 | 04/09/2024 | 05/09/2024 | 09/09/2024 | 12/09/2024 | 19/09/2024 |
| C57 | 24/09/2024 | 25/09/2024 | 02/10/2024 | 03/10/2024 | 07/10/2024 | 10/10/2024 | 17/10/2024 |
| C58 | 22/10/2024 | 23/10/2024 | 30/10/2024 | 31/10/2024 | 04/11/2024 | 07/11/2024 | 14/11/2024 |
| C59 | 19/11/2024 | 20/11/2024 | 27/11/2024 | 28/11/2024 | 02/12/2024 | 05/12/2024 | 12/12/2024 |

(¹) This timetable is only applicable when minor issues remain.

(*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(**) Comments from CHMP members are not made available to Marketing Authorisation Holders.

(***) An updated AR is optional and dependent on the comments received from CHMP members which create the need for the update.