



9 February 2022
EMA/825018/2015 Rev.3
Human Medicines Division

The timetables in this document may be subject to revision

Annual renewal application of conditional marketing authorisation - ATMP*

[Assessment of initial submission \(60-day timetable\)](#)

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

(*) This type of application applies to conditional marketing authorisations granted in accordance with Article 14(7) of Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006

Assessment of initial submission

60-day timetable

| | Deadline for Submission (*) | Start date (^) | CAT and PRAC Rapporteur Joint AR | Comments from PRAC, CAT and CHMP (**) | Updated CAT and PRAC Rapporteur Joint AR (***) | PRAC outcome | CAT Request for Supplementary Information (RSI) or Opinion | CHMP Opinion (#) |
|-----|-----------------------------|----------------|----------------------------------|---------------------------------------|--|--------------|--|------------------|
| A1 | 10/01/2020 | 27/01/2020 | 27/02/2020 | 03/03/2020 | 05/03/2020 | 12/03/2020 | 20/03/2020 | 26/03/2020 |
| A2 | 14/02/2020 | 02/03/2020 | 02/04/2020 | 07/04/2020 | 08/04/2020 | 17/04/2020 | 24/04/2020 | 30/04/2020 |
| A3 | 11/03/2020 | 28/03/2020 | 30/04/2020 | 05/05/2020 | 07/05/2020 | 14/05/2020 | 20/05/2020 | 28/05/2020 |
| A4 | 08/04/2020 | 27/04/2020 | 28/05/2020 | 02/06/2020 | 04/06/2020 | 11/06/2020 | 19/06/2020 | 25/06/2020 |
| A5 | 08/05/2020 | 25/05/2020 | 25/06/2020 | 30/06/2020 | 02/07/2020 | 09/07/2020 | 17/07/2020 | 23/07/2020 |
| A6 | | | | | | | | |
| A7 | 03/07/2020 | 20/07/2020 | 20/08/2020 | 25/08/2020 | 27/08/2020 | 04/09/2020 | 11/09/2020 | 17/09/2020 |
| A8 | 31/07/2020 | 17/08/2020 | 17/09/2020 | 22/09/2020 | 24/09/2020 | 01/10/2020 | 09/10/2020 | 15/10/2020 |
| A9 | 28/08/2020 | 14/09/2020 | 15/10/2020 | 20/10/2020 | 22/10/2020 | 29/10/2020 | 06/11/2020 | 12/11/2020 |
| A10 | 25/09/2020 | 12/10/2020 | 12/11/2020 | 17/11/2020 | 19/11/2020 | 26/11/2020 | 04/12/2020 | 10/12/2020 |
| A11 | 13/11/2020 | 30/11/2020 | 04/01/2021 | 06/01/2021 | 07/01/2021 | 14/01/2021 | 22/01/2021 | 28/01/2021 |
| A12 | 11/12/2020 | 28/12/2020 | 28/01/2021 | 02/02/2021 | 04/02/2021 | 11/02/2021 | 19/02/2021 | 25/02/2021 |
| A13 | 08/01/2021 | 25/01/2021 | 25/02/2021 | 02/03/2021 | 04/03/2021 | 11/03/2021 | 19/03/2021 | 25/03/2021 |
| A14 | 05/02/2021 | 22/02/2021 | 25/03/2021 | 30/03/2021 | 31/03/2021 | 09/04/2021 | 16/04/2021 | 22/04/2021 |
| A15 | 03/03/2021 | 20/03/2021 | 22/04/2021 | 27/04/2021 | 29/04/2021 | 06/05/2021 | 12/05/2021 | 20/05/2021 |
| A16 | 09/04/2021 | 26/04/2021 | 27/05/2021 | 01/06/2021 | 03/06/2021 | 10/06/2021 | 18/06/2021 | 24/06/2021 |
| A17 | 07/05/2021 | 24/05/2021 | 24/06/2021 | 29/06/2021 | 01/07/2021 | 08/07/2021 | 16/07/2021 | 22/07/2021 |
| A18 | | | | | | | | |
| A19 | 02/07/2021 | 19/07/2021 | 19/08/2021 | 24/08/2021 | 26/08/2021 | 03/09/2021 | 10/09/2021 | 16/09/2021 |
| A20 | 30/07/2021 | 16/08/2021 | 16/09/2021 | 21/09/2021 | 23/09/2021 | 30/09/2021 | 08/10/2021 | 14/10/2021 |
| A21 | 27/08/2021 | 13/09/2021 | 14/10/2021 | 19/10/2021 | 21/10/2021 | 28/10/2021 | 05/11/2021 | 11/11/2021 |
| A22 | 01/10/2021 | 18/10/2021 | 18/11/2021 | 23/11/2021 | 25/11/2021 | 02/12/2021 | 10/12/2021 | 16/12/2021 |
| A23 | 12/11/2021 | 29/11/2021 | 03/01/2022 | 04/01/2022 | 06/01/2022 | 13/01/2022 | 21/01/2022 | 27/01/2022 |
| A24 | 26/11/2021 | 27/12/2021 | 27/01/2022 | 01/02/2022 | 03/02/2022 | 10/02/2022 | 18/02/2022 | 24/02/2022 |
| A25 | 07/01/2022 | 24/01/2022 | 24/02/2022 | 01/03/2022 | 03/03/2022 | 10/03/2022 | 18/03/2022 | 24/03/2022 |
| A26 | 02/02/2022 | 19/02/2022 | 24/03/2022 | 29/03/2022 | 31/03/2022 | 07/04/2022 | 13/04/2022 | 22/04/2022 |
| A27 | 04/03/2022 | 21/03/2022 | 21/04/2022 | 26/04/2022 | 28/04/2022 | 05/05/2022 | 13/05/2022 | 19/05/2022 |
| A28 | 08/04/2022 | 25/04/2022 | 25/05/2022 | 31/05/2022 | 02/06/2022 | 10/06/2022 | 17/06/2022 | 23/06/2022 |
| A29 | 06/05/2022 | 23/05/2022 | 23/06/2022 | 28/06/2022 | 30/06/2022 | 07/07/2022 | 15/07/2022 | 21/07/2022 |
| A30 | | | | | | | | |
| A31 | 01/07/2022 | 18/07/2022 | 18/08/2022 | 23/08/2022 | 25/08/2022 | 01/09/2022 | 09/09/2022 | 15/09/2022 |
| A32 | 29/07/2022 | 15/08/2022 | 15/09/2022 | 20/09/2022 | 22/09/2022 | 29/09/2022 | 07/10/2022 | 13/10/2022 |
| A33 | 26/08/2022 | 12/09/2022 | 13/10/2022 | 18/10/2022 | 20/10/2022 | 27/10/2022 | 04/11/2022 | 10/11/2022 |
| A34 | 30/09/2022 | 17/10/2022 | 17/11/2022 | 22/11/2022 | 24/11/2022 | 01/12/2022 | 09/12/2022 | 15/12/2022 |
| A35 | 11/11/2022 | 28/11/2022 | 22/12/2022 | 03/01/2023 | 05/01/2023 | 12/01/2023 | 20/01/2023 | 26/01/2023 |
| A36 | 25/11/2022 | 26/12/2022 | 26/01/2023 | 31/01/2023 | 02/02/2023 | 09/02/2023 | 17/02/2023 | 23/02/2023 |
| A37 | 13/01/2023 | 30/01/2023 | 02/03/2023 | 07/03/2023 | 09/03/2023 | 16/03/2023 | 24/03/2023 | 30/03/2023 |
| A38 | 10/02/2023 | 27/02/2023 | 30/03/2023 | 03/04/2023 | 05/04/2023 | 14/04/2023 | 21/04/2023 | 26/04/2023 |
| A39 | 08/03/2023 | 25/03/2023 | 28/04/2023 | 02/05/2023 | 04/05/2023 | 12/05/2023 | 17/05/2023 | 25/05/2023 |
| A40 | 05/04/2023 | 24/04/2023 | 25/05/2023 | 30/05/2023 | 01/06/2023 | 08/06/2023 | 16/06/2023 | 22/06/2023 |
| A41 | 05/05/2023 | 22/05/2023 | 22/06/2023 | 27/06/2023 | 29/06/2023 | 06/07/2023 | 14/07/2023 | 20/07/2023 |
| A42 | | | | | | | | |
| A43 | 30/06/2023 | 17/07/2023 | 17/08/2023 | 22/08/2023 | 24/08/2023 | 31/08/2023 | 08/09/2023 | 14/09/2023 |
| A44 | 28/07/2023 | 14/08/2023 | 14/09/2023 | 19/09/2023 | 21/09/2023 | 28/09/2023 | 06/10/2023 | 12/10/2023 |
| A45 | 22/08/2023 | 08/09/2023 | 12/10/2023 | 17/10/2023 | 19/10/2023 | 26/10/2023 | 31/10/2023 | 09/11/2023 |
| A46 | 29/09/2023 | 16/10/2023 | 16/11/2023 | 21/11/2023 | 23/11/2023 | 30/11/2023 | 08/12/2023 | 14/12/2023 |
| A47 | 10/11/2023 | 27/11/2023 | 03/01/2024 | 04/01/2024 | 05/01/2024 | 11/01/2024 | 19/01/2024 | 25/01/2024 |

| | Deadline for Submission (*) | Start date (^) | CAT and PRAC Rapporteur Joint AR | Comments from PRAC, CAT and CHMP (**) | Updated CAT and PRAC Rapporteur Joint AR (***) | PRAC outcome | CAT Request for Supplementary Information (RSI) or Opinion | CHMP Opinion (#) |
|-----|-----------------------------|----------------|----------------------------------|---------------------------------------|--|--------------|--|------------------|
| A48 | 24/11/2023 | 25/12/2023 | 25/01/2024 | 30/01/2024 | 01/02/2024 | 08/02/2024 | 16/02/2024 | 22/02/2024 |
| A49 | 05/01/2024 | 22/01/2024 | 22/02/2024 | 27/02/2024 | 29/02/2024 | 07/03/2024 | 15/03/2024 | 21/03/2024 |
| A50 | 09/02/2024 | 26/02/2024 | 27/03/2024 | 02/04/2024 | 04/04/2024 | 11/04/2024 | 19/04/2024 | 25/04/2024 |
| A51 | 15/03/2024 | 01/04/2024 | 02/05/2024 | 06/05/2024 | 08/05/2024 | 16/05/2024 | 24/05/2024 | 30/05/2024 |
| A52 | 12/04/2024 | 29/04/2024 | 30/05/2024 | 04/06/2024 | 06/06/2024 | 13/06/2024 | 21/06/2024 | 27/06/2024 |
| A53 | 08/05/2024 | 27/05/2024 | 27/06/2024 | 02/07/2024 | 04/07/2024 | 11/07/2024 | 19/07/2024 | 25/07/2024 |
| A54 | | | | | | | | |
| A55 | 05/07/2024 | 22/07/2024 | 22/08/2024 | 27/08/2024 | 29/08/2024 | 05/09/2024 | 13/09/2024 | 19/09/2024 |
| A56 | 02/08/2024 | 19/08/2024 | 19/09/2024 | 24/09/2024 | 26/09/2024 | 03/10/2024 | 11/10/2024 | 17/10/2024 |
| A57 | 30/08/2024 | 16/09/2024 | 17/10/2024 | 22/10/2024 | 24/10/2024 | 31/10/2024 | 08/11/2024 | 14/11/2024 |
| A58 | 27/09/2024 | 14/10/2024 | 14/11/2024 | 19/11/2024 | 21/11/2024 | 28/11/2024 | 06/12/2024 | 12/12/2024 |

(*) Renewal applications must be submitted at least six months before the actual expiry date of the marketing authorisation, i.e. the 1-year anniversary of the Commission Decision granting or renewing the marketing authorisation and irrespective of whether the marketing authorisation may be suspended. The start of the evaluation process will be the next possible date in the table after submission and validation of the dossier. The MAHs should agree in advance the submission date of the renewal application with the Agency.

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, CAT and CHMP members are not made available to Marketing Authorisation Holders (MAHs).

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

(#) Step applicable only in case of CAT Opinion (not applicable in case a Request for Supplementary Information is adopted by the CAT).

Assessment of responses to Request for Supplementary Information

30-day timetable after immediate responses

| | Deadline for Submission (*) | Re-start date | CAT and PRAC Rapporteur Joint AR | PRAC outcome | Comments from CAT and CHMP (**) | Updated CAT and PRAC Rapporteur Joint AR (***) | CAT Opinion | CHMP Opinion |
|-----|-----------------------------|---------------|----------------------------------|--------------|---------------------------------|--|-------------|--------------|
| C1 | 30/01/2020 | 31/01/2020 | 11/02/2020 | 13/02/2020 | 14/02/2020 | 17/02/2020 | 21/02/2020 | 27/02/2020 |
| C2 | 27/02/2020 | 28/02/2020 | 10/03/2020 | 12/03/2020 | 13/03/2020 | 16/03/2020 | 20/03/2020 | 26/03/2020 |
| C3 | 27/03/2020 | 30/03/2020 | 14/04/2020 | 17/04/2020 | 17/04/2020 | 20/04/2020 | 24/04/2020 | 30/04/2020 |
| C4 | 28/04/2020 | 29/04/2020 | 11/05/2020 | 14/05/2020 | 13/05/2020 | 15/05/2020 | 20/05/2020 | 28/05/2020 |
| C5 | 28/05/2020 | 29/05/2020 | 09/06/2020 | 11/06/2020 | 12/06/2020 | 15/06/2020 | 19/06/2020 | 25/06/2020 |
| C6 | 25/06/2020 | 26/06/2020 | 07/07/2020 | 09/07/2020 | 10/07/2020 | 13/07/2020 | 17/07/2020 | 23/07/2020 |
| C7 | | | | | | | | |
| C8 | 14/08/2020 | 17/08/2020 | 01/09/2020 | 04/09/2020 | 04/09/2020 | 07/09/2020 | 11/09/2020 | 17/09/2020 |
| C9 | 17/09/2020 | 18/09/2020 | 29/09/2020 | 01/10/2020 | 02/10/2020 | 05/10/2020 | 09/10/2020 | 15/10/2020 |
| C10 | 15/10/2020 | 16/10/2020 | 27/10/2020 | 29/10/2020 | 30/10/2020 | 03/11/2020 | 06/11/2020 | 12/11/2020 |
| C11 | 12/11/2020 | 13/11/2020 | 24/11/2020 | 26/11/2020 | 27/11/2020 | 30/11/2020 | 04/12/2020 | 10/12/2020 |
| C12 | 23/12/2020 | 28/12/2020 | 12/01/2021 | 14/01/2021 | 15/01/2021 | 18/01/2021 | 22/01/2021 | 28/01/2021 |
| C13 | 28/01/2021 | 29/01/2021 | 09/02/2021 | 11/02/2021 | 12/02/2021 | 15/02/2021 | 19/02/2021 | 25/02/2021 |
| C14 | 25/02/2021 | 26/02/2021 | 09/03/2021 | 11/03/2021 | 12/03/2021 | 15/03/2021 | 19/03/2021 | 25/03/2021 |
| C15 | 25/03/2021 | 26/03/2021 | 06/04/2021 | 09/04/2021 | 09/04/2021 | 12/04/2021 | 16/04/2021 | 22/04/2021 |
| C16 | 20/04/2021 | 21/04/2021 | 03/05/2021 | 06/05/2021 | 05/05/2021 | 07/05/2021 | 12/05/2021 | 20/05/2021 |
| C17 | 21/05/2021 | 25/05/2021 | 08/06/2021 | 10/06/2021 | 11/06/2021 | 14/06/2021 | 18/06/2021 | 24/06/2021 |
| C18 | 24/06/2021 | 25/06/2021 | 06/07/2021 | 08/07/2021 | 09/07/2021 | 12/07/2021 | 16/07/2021 | 22/07/2021 |
| C19 | | | | | | | | |
| C20 | 19/08/2021 | 20/08/2021 | 31/08/2021 | 03/09/2021 | 03/09/2021 | 06/09/2021 | 10/09/2021 | 16/09/2021 |
| C21 | 16/09/2021 | 17/09/2021 | 28/09/2021 | 30/09/2021 | 01/10/2021 | 04/10/2021 | 08/10/2021 | 14/10/2021 |
| C22 | 14/10/2021 | 15/10/2021 | 26/10/2021 | 28/10/2021 | 29/10/2021 | 29/10/2021 | 05/11/2021 | 11/11/2021 |
| C23 | 12/11/2021 | 15/11/2021 | 30/11/2021 | 02/12/2021 | 03/12/2021 | 06/12/2021 | 10/12/2021 | 16/12/2021 |
| C24 | 22/12/2021 | 23/12/2021 | 11/01/2022 | 13/01/2022 | 14/01/2022 | 17/01/2022 | 21/01/2022 | 27/01/2022 |
| C25 | 27/01/2022 | 28/01/2022 | 08/02/2022 | 10/02/2022 | 11/02/2022 | 14/02/2022 | 18/02/2022 | 24/02/2022 |
| C26 | 24/02/2022 | 25/02/2022 | 08/03/2022 | 10/03/2022 | 11/03/2022 | 14/03/2022 | 18/03/2022 | 24/03/2022 |
| C27 | 22/03/2022 | 23/03/2022 | 04/04/2022 | 07/04/2022 | 06/04/2022 | 08/04/2022 | 13/04/2022 | 22/04/2022 |
| C28 | 21/04/2022 | 22/04/2022 | 03/05/2022 | 05/05/2022 | 06/05/2022 | 10/05/2022 | 13/05/2022 | 19/05/2022 |
| C29 | 20/05/2022 | 23/05/2022 | 07/06/2022 | 10/06/2022 | 10/06/2022 | 13/06/2022 | 17/06/2022 | 23/06/2022 |
| C30 | 23/06/2022 | 24/06/2022 | 05/07/2022 | 07/07/2022 | 08/07/2022 | 11/07/2022 | 15/07/2022 | 21/07/2022 |
| C31 | | | | | | | | |
| C32 | 10/08/2022 | 11/08/2022 | 30/08/2022 | 01/09/2022 | 02/09/2022 | 05/09/2022 | 09/09/2022 | 15/09/2022 |
| C33 | 15/09/2022 | 16/09/2022 | 27/09/2022 | 29/09/2022 | 30/09/2022 | 03/10/2022 | 07/10/2022 | 13/10/2022 |
| C34 | 13/10/2022 | 14/10/2022 | 25/10/2022 | 27/10/2022 | 27/10/2022 | 28/10/2022 | 04/11/2022 | 10/11/2022 |
| C35 | 11/11/2022 | 14/11/2022 | 29/11/2022 | 01/12/2022 | 02/12/2022 | 05/12/2022 | 09/12/2022 | 15/12/2022 |
| C36 | 21/12/2022 | 22/12/2022 | 10/01/2023 | 12/01/2023 | 13/01/2023 | 16/01/2023 | 20/01/2023 | 26/01/2023 |
| C37 | 26/01/2023 | 27/01/2023 | 07/02/2023 | 09/02/2023 | 10/02/2023 | 13/02/2023 | 17/02/2023 | 23/02/2023 |
| C38 | 24/02/2023 | 27/02/2023 | 14/03/2023 | 16/03/2023 | 17/03/2023 | 20/03/2023 | 24/03/2023 | 30/03/2023 |
| C39 | 30/03/2023 | 31/03/2023 | 11/04/2023 | 14/04/2023 | 14/04/2023 | 17/04/2023 | 21/04/2023 | 26/04/2023 |
| C40 | 25/04/2023 | 26/04/2023 | 08/05/2023 | 12/05/2023 | 10/05/2023 | 12/05/2023 | 17/05/2023 | 25/05/2023 |
| C41 | 25/05/2023 | 26/05/2023 | 06/06/2023 | 08/06/2023 | 09/06/2023 | 12/06/2023 | 16/06/2023 | 22/06/2023 |
| C42 | 22/06/2023 | 23/06/2023 | 04/07/2023 | 06/07/2023 | 07/07/2023 | 10/07/2023 | 14/07/2023 | 20/07/2023 |
| C43 | | | | | | | | |
| C44 | 09/08/2023 | 10/08/2023 | 29/08/2023 | 31/08/2023 | 01/09/2023 | 04/09/2023 | 08/09/2023 | 14/09/2023 |

| | Deadline for Submission (*) | Re-start date | CAT and PRAC Rapporteur Joint AR | PRAC outcome | Comments from CAT and CHMP (**) | Updated CAT and PRAC Rapporteur Joint AR (***) | CAT Opinion | CHMP Opinion |
|-----|-----------------------------|---------------|----------------------------------|--------------|---------------------------------|--|-------------|--------------|
| C45 | 14/09/2023 | 15/09/2023 | 26/09/2023 | 28/09/2023 | 29/09/2023 | 02/10/2023 | 06/10/2023 | 12/10/2023 |
| C46 | 09/10/2023 | 10/10/2023 | 20/10/2023 | 26/10/2023 | 24/10/2023 | 27/10/2023 | 31/10/2023 | 09/11/2023 |
| C47 | 08/11/2023 | 09/11/2023 | 28/11/2023 | 30/11/2023 | 01/12/2023 | 04/12/2023 | 08/12/2023 | 14/12/2023 |
| C48 | 20/12/2023 | 21/12/2023 | 09/01/2024 | 11/01/2024 | 12/01/2024 | 15/01/2024 | 19/01/2024 | 25/01/2024 |
| C49 | 25/01/2024 | 26/01/2024 | 06/02/2024 | 08/02/2024 | 09/02/2024 | 12/02/2024 | 16/02/2024 | 22/02/2024 |
| C50 | 22/02/2024 | 23/02/2024 | 05/03/2024 | 07/03/2024 | 08/03/2024 | 11/03/2024 | 15/03/2024 | 21/03/2024 |
| C51 | 22/03/2024 | 25/03/2024 | 09/04/2024 | 11/04/2024 | 12/04/2024 | 15/04/2024 | 19/04/2024 | 25/04/2024 |
| C52 | 26/04/2024 | 29/04/2024 | 14/05/2024 | 16/05/2024 | 17/05/2024 | 21/05/2024 | 24/05/2024 | 30/05/2024 |
| C53 | 30/05/2024 | 31/05/2024 | 11/06/2024 | 13/06/2024 | 14/06/2024 | 17/06/2024 | 21/06/2024 | 27/06/2024 |
| C54 | 27/06/2024 | 28/06/2024 | 09/07/2024 | 11/07/2024 | 12/07/2024 | 15/07/2024 | 19/07/2024 | 25/07/2024 |
| C55 | | | | | | | | |
| C56 | 14/08/2024 | 15/08/2024 | 03/09/2024 | 05/09/2024 | 06/09/2024 | 09/09/2024 | 13/09/2024 | 19/09/2024 |
| C57 | 19/09/2024 | 20/09/2024 | 01/10/2024 | 03/10/2024 | 04/10/2024 | 07/10/2024 | 11/10/2024 | 17/10/2024 |
| C58 | 17/10/2024 | 18/10/2024 | 29/10/2024 | 31/10/2024 | 31/10/2024 | 04/11/2024 | 08/11/2024 | 14/11/2024 |
| C59 | 14/11/2024 | 15/11/2024 | 26/11/2024 | 28/11/2024 | 29/11/2024 | 02/12/2024 | 06/12/2024 | 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 CAT and CHMP members are not made available to Marketing Authorisation Holders (MAHs).

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