



9 February 2023  
EMA/119185/2015 Rev.11  
Human Medicines Division

The timetables in this document may be subject to revision

## Initial (Full) Marketing Authorisation application assessment timetables

[Assessment of initial submission \(120-day timetable\)](#)

[Assessment of responses to List of Questions \(60-day timetable after clock-stop for submission of responses\)](#)

[Assessment of responses to List of Outstanding Issues \(30-day timetable after clock-stop for responses\)](#)

[Assessment of responses to List of Outstanding Issues \(30-day timetable after immediate responses\)](#)

[Assessment of Outstanding Issues following Oral Explanation \(30-day timetable\)](#)

## Assessment of initial submission (120-day timetable)

|     | Deadline for Submission (*) | Start date (^) | CHMP (Co) Rapporteur ARs (***) | PRAC Rapporteur AR and CHMP Co-Rapporteur assessment (***) | Comments from PRAC (**) | Comments from CHMP (**) | Early draft LOQ (for Peer review tele-conference) (#) | PRAC outcome (~) | Updated PRAC Rapporteur AR | Peer review tele-conference (TC) | Draft LoQ  | List of Questions (LoQ) or Opinion |
|-----|-----------------------------|----------------|--------------------------------|--|-------------------------|-------------------------|---|------------------|----------------------------|----------------------------------|------------|------------------------------------|
| A1  | 13/01/2020                  | 30/01/2020     | 20/04/2020                     | 04/05/2020   | 08/05/2020              | 08/05/2020              | 14/05/2020  | 14/05/2020       | 14/05/2020                 | 18/05/2020                       | 20/05/2020 | 28/05/2020                         |
| A2  | 10/02/2020                  | 27/02/2020     | 18/05/2020                     | 01/06/2020   | 05/06/2020              | 05/06/2020              | 11/06/2020  | 11/06/2020       | 11/06/2020                 | 15/06/2020                       | 18/06/2020 | 25/06/2020                         |
| A3  | 09/03/2020                  | 26/03/2020     | 15/06/2020                     | 29/06/2020   | 03/07/2020              | 03/07/2020              | 09/07/2020  | 09/07/2020       | 09/07/2020                 | 13/07/2020                       | 16/07/2020 | 23/07/2020                         |
| A4  |                             |                |                                |  |                         |                         |   |                  |                            |                                  |            |                                    |
| A5  | 04/05/2020                  | 21/05/2020     | 10/08/2020                     | 24/08/2020   | 28/08/2020              | 28/08/2020              | 03/09/2020  | 04/09/2020       | 04/09/2020                 | 07/09/2020                       | 10/09/2020 | 17/09/2020                         |
| A6  | 01/06/2020                  | 18/06/2020     | 07/09/2020                     | 21/09/2020   | 25/09/2020              | 25/09/2020              | 01/10/2020  | 01/10/2020       | 01/10/2020                 | 05/10/2020                       | 08/10/2020 | 15/10/2020                         |
| A7  | 29/06/2020                  | 16/07/2020     | 05/10/2020                     | 19/10/2020   | 23/10/2020              | 23/10/2020              | 29/10/2020  | 29/10/2020       | 29/10/2020                 | 03/11/2020                       | 05/11/2020 | 12/11/2020                         |
| A8  | 27/07/2020                  | 13/08/2020     | 03/11/2020                     | 16/11/2020   | 20/11/2020              | 20/11/2020              | 26/11/2020  | 26/11/2020       | 26/11/2020                 | 30/11/2020                       | 03/12/2020 | 10/12/2020                         |
| A9  | 14/09/2020                  | 01/10/2020     | 21/12/2020                     | 04/01/2021   | 08/01/2021              | 08/01/2021              | 14/01/2021  | 14/01/2021       | 14/01/2021                 | 18/01/2021                       | 21/01/2021 | 28/01/2021                         |
| A10 | 12/10/2020                  | 29/10/2020     | 18/01/2021                     | 01/02/2021   | 05/02/2021              | 05/02/2021              | 11/02/2021  | 11/02/2021       | 11/02/2021                 | 15/02/2021                       | 18/02/2021 | 25/02/2021                         |
| A11 | 09/11/2020                  | 26/11/2020     | 15/02/2021                     | 01/03/2021   | 05/03/2021              | 05/03/2021              | 11/03/2021  | 11/03/2021       | 11/03/2021                 | 15/03/2021                       | 18/03/2021 | 25/03/2021                         |
| A12 | 23/11/2020                  | 24/12/2020     | 15/03/2021                     | 29/03/2021   | 31/03/2021              | 31/03/2021              | 08/04/2021  | 09/04/2021       | 09/04/2021                 | 12/04/2021                       | 15/04/2021 | 22/04/2021                         |
| A13 | 04/01/2021                  | 21/01/2021     | 12/04/2021                     | 26/04/2021   | 30/04/2021              | 30/04/2021              | 06/05/2021  | 06/05/2021       | 06/05/2021                 | 10/05/2021                       | 12/05/2021 | 20/05/2021                         |
| A14 | 08/02/2021                  | 25/02/2021     | 17/05/2021                     | 31/05/2021   | 04/06/2021              | 07/06/2021              | 10/06/2021  | 10/06/2021       | 10/06/2021                 | 14/06/2021                       | 17/06/2021 | 24/06/2021                         |
| A15 | 08/03/2021                  | 25/03/2021     | 14/06/2021                     | 28/06/2021   | 02/07/2021              | 05/07/2021              | 08/07/2021  | 08/07/2021       | 08/07/2021                 | 12/07/2021                       | 15/07/2021 | 22/07/2021                         |
| A16 |                             |                |                                |  |                         |                         |   |                  |                            |                                  |            |                                    |
| A17 | 30/04/2021                  | 20/05/2021     | 09/08/2021                     | 23/08/2021   | 27/08/2021              | 30/08/2021              | 02/09/2021  | 03/09/2021       | 03/09/2021                 | 06/09/2021                       | 09/09/2021 | 16/09/2021                         |
| A18 | 31/05/2021                  | 17/06/2021     | 06/09/2021                     | 20/09/2021   | 24/09/2021              | 27/09/2021              | 30/09/2021  | 30/09/2021       | 30/09/2021                 | 04/10/2021                       | 07/10/2021 | 14/10/2021                         |
| A19 | 28/06/2021                  | 15/07/2021     | 04/10/2021                     | 18/10/2021   | 22/10/2021              | 25/10/2021              | 27/10/2021  | 28/10/2021       | 28/10/2021                 | 29/10/2021                       | 04/11/2021 | 11/11/2021                         |
| A20 | 02/08/2021                  | 19/08/2021     | 08/11/2021                     | 22/11/2021   | 26/11/2021              | 29/11/2021              | 02/12/2021  | 02/12/2021       | 02/12/2021                 | 06/12/2021                       | 09/12/2021 | 16/12/2021                         |
| A21 | 13/09/2021                  | 30/09/2021     | 20/12/2021                     | 03/01/2022   | 07/01/2022              | 10/01/2022              | 13/01/2022  | 13/01/2022       | 13/01/2022                 | 17/01/2022                       | 20/01/2022 | 27/01/2022                         |
| A22 | 11/10/2021                  | 28/10/2021     | 17/01/2022                     | 31/01/2022   | 04/02/2022              | 07/02/2022              | 10/02/2022  | 10/02/2022       | 10/02/2022                 | 14/02/2022                       | 17/02/2022 | 24/02/2022                         |
| A23 | 08/11/2021                  | 25/11/2021     | 14/02/2022                     | 28/02/2022   | 04/03/2022              | 07/03/2022              | 10/03/2022  | 10/03/2022       | 10/03/2022                 | 14/03/2022                       | 17/03/2022 | 24/03/2022                         |
| A24 | 29/11/2021                  | 24/12/2021     | 14/03/2022                     | 28/03/2022   | 01/04/2022              | 04/04/2022              | 07/04/2022  | 07/04/2022       | 07/04/2022                 | 11/04/2022                       | 13/04/2022 | 22/04/2022                         |

|     | Deadline for Submission (*) | Start date (^) | CHMP (Co) Rapporteur ARs (***) | PRAC Rapporteur AR and CHMP Co-Rapporteur assessment (***) | Comments from PRAC (**) | Comments from CHMP (**) | Early draft LOQ (for Peer review tele-conference) (#) | PRAC outcome (~) | Updated PRAC Rapporteur AR | Peer review tele-conference (TC) | Draft LoQ  | List of Questions (LoQ) or Opinion |
|-----|-----------------------------|----------------|--------------------------------|--|-------------------------|-------------------------|---|------------------|----------------------------|----------------------------------|------------|------------------------------------|
| A25 | 03/01/2022                  | 20/01/2022     | 11/04/2022                     | 25/04/2022   | 29/04/2022              | 02/05/2022              | 05/05/2022  | 05/05/2022       | 05/05/2022                 | 10/05/2022                       | 12/05/2022 | 19/05/2022                         |
| A26 | 07/02/2022                  | 24/02/2022     | 16/05/2022                     | 30/05/2022   | 03/06/2022              | 06/06/2022              | 10/06/2022  | 10/06/2022       | 10/06/2022                 | 13/06/2022                       | 16/06/2022 | 23/06/2022                         |
| A27 | 07/03/2022                  | 24/03/2022     | 13/06/2022                     | 27/06/2022   | 01/07/2022              | 04/07/2022              | 07/07/2022  | 07/07/2022       | 07/07/2022                 | 11/07/2022                       | 14/07/2022 | 21/07/2022                         |
| A28 |                             |                |                                |  |                         |                         |   |                  |                            |                                  |            |                                    |
| A29 | 02/05/2022                  | 19/05/2022     | 08/08/2022                     | 22/08/2022   | 26/08/2022              | 29/08/2022              | 01/09/2022  | 01/09/2022       | 01/09/2022                 | 05/09/2022                       | 08/09/2022 | 15/09/2022                         |
| A30 | 30/05/2022                  | 16/06/2022     | 05/09/2022                     | 19/09/2022   | 23/09/2022              | 26/09/2022              | 29/09/2022  | 29/09/2022       | 29/09/2022                 | 03/10/2022                       | 06/10/2022 | 13/10/2022                         |
| A31 | 27/06/2022                  | 14/07/2022     | 03/10/2022                     | 17/10/2022   | 21/10/2022              | 24/10/2022              | 27/10/2022  | 27/10/2022       | 27/10/2022                 | 28/10/2022                       | 03/11/2022 | 10/11/2022                         |
| A32 | 01/08/2022                  | 18/08/2022     | 07/11/2022                     | 21/11/2022   | 25/11/2022              | 28/11/2022              | 01/12/2022  | 01/12/2022       | 01/12/2022                 | 05/12/2022                       | 08/12/2022 | 15/12/2022                         |
| A33 | 12/09/2022                  | 29/09/2022     | 19/12/2022                     | 03/01/2023   | 06/01/2023              | 09/01/2023              | 12/01/2023  | 12/01/2023       | 12/01/2023                 | 16/01/2023                       | 19/01/2023 | 26/01/2023                         |
| A34 | 10/10/2022                  | 27/10/2022     | 16/01/2023                     | 30/01/2023   | 03/02/2023              | 06/02/2023              | 09/02/2023  | 09/02/2023       | 09/02/2023                 | 13/02/2023                       | 16/02/2023 | 23/02/2023                         |
| A35 | 14/11/2022                  | 01/12/2022     | 20/02/2023                     | 06/03/2023   | 10/03/2023              | 13/03/2023              | 16/03/2023  | 16/03/2023       | 16/03/2023                 | 20/03/2023                       | 23/03/2023 | 30/03/2023                         |
| A36 | 28/11/2022                  | 28/12/2022     | 20/03/2023                     | 03/04/2023   | 05/04/2023              | 08/04/2023              | 14/04/2023  | 14/04/2023       | 14/04/2023                 | 17/04/2023                       | 20/04/2023 | 26/04/2023                         |
| A37 | 09/01/2023                  | 26/01/2023     | 17/04/2023                     | 02/05/2023   | 05/05/2023              | 08/05/2023              | 12/05/2023  | 12/05/2023       | 12/05/2023                 | 15/05/2023                       | 17/05/2023 | 25/05/2023                         |
| A38 | 06/02/2023                  | 23/02/2023     | 15/05/2023                     | 30/05/2023   | 02/06/2023              | 05/06/2023              | 08/06/2023  | 08/06/2023       | 08/06/2023                 | 12/06/2023                       | 15/06/2023 | 22/06/2023                         |
| A39 | 06/03/2023                  | 23/03/2023     | 12/06/2023                     | 26/06/2023   | 30/06/2023              | 03/07/2023              | 06/07/2023  | 06/07/2023       | 06/07/2023                 | 10/07/2023                       | 13/07/2023 | 20/07/2023                         |
| A40 |                             |                |                                |  |                         |                         |   |                  |                            |                                  |            |                                    |
| A41 | 26/04/2023                  | 18/05/2023     | 07/08/2023                     | 21/08/2023   | 25/08/2023              | 28/08/2023              | 31/08/2023  | 31/08/2023       | 31/08/2023                 | 04/09/2023                       | 07/09/2023 | 14/09/2023                         |
| A42 | 26/05/2023                  | 15/06/2023     | 04/09/2023                     | 18/09/2023   | 22/09/2023              | 25/09/2023              | 28/09/2023  | 28/09/2023       | 28/09/2023                 | 02/10/2023                       | 05/10/2023 | 12/10/2023                         |
| A43 | 26/06/2023                  | 13/07/2023     | 02/10/2023                     | 16/10/2023   | 20/10/2023              | 23/10/2023              | 26/10/2023  | 26/10/2023       | 26/10/2023                 | 30/10/2023                       | 31/10/2023 | 09/11/2023                         |
| A44 | 31/07/2023                  | 17/08/2023     | 06/11/2023                     | 20/11/2023   | 24/11/2023              | 27/11/2023              | 30/11/2023  | 30/11/2023       | 30/11/2023                 | 04/12/2023                       | 07/12/2023 | 14/12/2023                         |
| A45 | 11/09/2023                  | 28/09/2023     | 18/12/2023                     | 03/01/2024   | 05/01/2024              | 08/01/2024              | 11/01/2024  | 11/01/2024       | 11/01/2024                 | 15/01/2024                       | 18/01/2024 | 25/01/2024                         |
| A46 | 09/10/2023                  | 26/10/2023     | 15/01/2024                     | 29/01/2024   | 02/02/2024              | 05/02/2024              | 08/02/2024  | 08/02/2024       | 08/02/2024                 | 12/02/2024                       | 15/02/2024 | 22/02/2024                         |
| A47 | 06/11/2023                  | 23/11/2023     | 12/02/2024                     | 26/02/2024   | 01/03/2024              | 04/03/2024              | 07/03/2024  | 07/03/2024       | 07/03/2024                 | 11/03/2024                       | 14/03/2024 | 21/03/2024                         |
| A48 | 27/11/2023                  | 28/12/2023     | 18/03/2024                     | 02/04/2024   | 05/04/2024              | 08/04/2024              | 11/04/2024  | 11/04/2024       | 11/04/2024                 | 15/04/2024                       | 18/04/2024 | 25/04/2024                         |
| A49 | 15/01/2024                  | 01/02/2024     | 22/04/2024                     | 06/05/2024   | 08/05/2024              | 08/05/2024              | 16/05/2024  | 16/05/2024       | 16/05/2024                 | 21/05/2024                       | 23/05/2024 | 30/05/2024                         |
| A50 | 12/02/2024                  | 29/02/2024     | 21/05/2024                     | 03/06/2024   | 07/06/2024              | 10/06/2024              | 13/06/2024  | 13/06/2024       | 13/06/2024                 | 17/06/2024                       | 20/06/2024 | 27/06/2024                         |

|     | Deadline for Submission (*) | Start date (^) | CHMP (Co) Rapporteur ARs (***) | PRAC Rapporteur AR and CHMP Co-Rapporteur assessment (***) | Comments from PRAC (**) | Comments from CHMP (**) | Early draft LOQ (for Peer review tele-conference) (#) | PRAC outcome (~) | Updated PRAC Rapporteur AR | Peer review telecon-ference (TC) | Draft LoQ  | List of Questions (LoQ) or Opinion |
|-----|-----------------------------|----------------|--------------------------------|--|-------------------------|-------------------------|---|------------------|----------------------------|----------------------------------|------------|------------------------------------|
| A51 | 11/03/2024                  | 28/03/2024     | 17/06/2024                     | 01/07/2024   | 05/07/2024              | 08/07/2024              | 11/07/2024  | 11/07/2024       | 11/07/2024                 | 15/07/2024                       | 18/07/2024 | 25/07/2024                         |
| A52 |                             |                |                                |  |                         |                         |   |                  |                            |                                  |            |                                    |
| A53 | 30/04/2024                  | 23/05/2024     | 12/08/2024                     | 26/08/2024   | 30/08/2024              | 02/09/2024              | 05/09/2024  | 05/09/2024       | 05/09/2024                 | 09/09/2024                       | 12/09/2024 | 19/09/2024                         |
| A54 | 03/06/2024                  | 20/06/2024     | 09/09/2024                     | 23/09/2024   | 27/09/2024              | 30/09/2024              | 03/10/2024  | 03/10/2024       | 03/10/2024                 | 07/10/2024                       | 10/10/2024 | 17/10/2024                         |
| A55 | 01/07/2024                  | 18/07/2024     | 07/10/2024                     | 21/10/2024   | 25/10/2024              | 28/10/2024              | 31/10/2024  | 31/10/2024       | 31/10/2024                 | 04/11/2024                       | 07/11/2024 | 14/11/2024                         |
| A56 | 29/07/2024                  | 15/08/2024     | 04/11/2024                     | 18/11/2024   | 22/11/2024              | 25/11/2024              | 28/11/2024  | 28/11/2024       | 28/11/2024                 | 02/12/2024                       | 05/12/2024 | 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.

(^) The validation period between submission date and start date is generally thirteen EMA working days. For further information about the dates on which the Agency will be closed during the current year, please refer to the business hours and holidays page on the website.

(\*\*) Comments from CHMP and PRAC members are not made available to Applicants.

(#) Peer review is a process by which other members of the CHMP review the (Co) Rapporteurs' scientific evaluation, as well as the validity of the scientific/regulatory conclusions reached. It applies during the initial phase of the assessment of a new Marketing Authorisation Application (MAA).

(~) PRAC discussion (and outcome) during the 1st assessment phase is only envisaged for a minority of applications.

(\*\*\*) The CHMP Co-Rapporteur introduces their assessment into the Rapporteur Day 80 Overview assessment report for non-COVID 19 related applications. The Rapporteur AR and Co-Rapporteur assessment will be both made available to the applicant.

## Assessment of responses to List of Questions (LOQ)

60-day timetable after clock-stop for submission of responses

|     | Deadline for Submission (*) | Restart    | CHMP and PRAC Rapporteurs Joint AR (JAR) | Comments from PRAC (**) | PRAC outcome (#) | Updated PRAC Rapporteur AR | Comments from CHMP (**) | Updated CHMP (and PRAC) Rapporteurs JAR (~) | List of Outstanding Issues (LoOI) or Opinion |
|-----|-----------------------------|------------|--|-------------------------|------------------|----------------------------|-------------------------|---|--|
| B1  | 24/01/2020                  | 27/01/2020 | 02/03/2020                               | 06/03/2020              | 12/03/2020       | 12/03/2020                 | 16/03/2020              | 19/03/2020                                  | 26/03/2020                                   |
| B2  | 28/02/2020                  | 02/03/2020 | 06/04/2020                               | 08/04/2020              | 17/04/2020       | 17/04/2020                 | 20/04/2020              | 23/04/2020                                  | 30/04/2020                                   |
| B3  | 27/03/2020                  | 30/03/2020 | 04/05/2020                               | 08/05/2020              | 14/05/2020       | 14/05/2020                 | 18/05/2020              | 20/05/2020                                  | 28/05/2020                                   |
| B4  | 24/04/2020                  | 27/04/2020 | 01/06/2020                               | 05/06/2020              | 11/06/2020       | 11/06/2020                 | 15/06/2020              | 18/06/2020                                  | 25/06/2020                                   |
| B5  | 22/05/2020                  | 25/05/2020 | 29/06/2020                               | 03/07/2020              | 09/07/2020       | 09/07/2020                 | 13/07/2020              | 16/07/2020                                  | 23/07/2020                                   |
| B6  |                             |            |  |                         |                  |                            |                         |   |  |
| B7  | 17/07/2020                  | 20/07/2020 | 24/08/2020                               | 28/08/2020              | 04/09/2020       | 04/09/2020                 | 07/09/2020              | 10/09/2020                                  | 17/09/2020                                   |
| B8  | 14/08/2020                  | 17/08/2020 | 21/09/2020                               | 25/09/2020              | 01/10/2020       | 01/10/2020                 | 05/10/2020              | 08/10/2020                                  | 15/10/2020                                   |
| B9  | 11/09/2020                  | 14/09/2020 | 19/10/2020                               | 23/10/2020              | 29/10/2020       | 29/10/2020                 | 03/11/2020              | 05/11/2020                                  | 12/11/2020                                   |
| B10 | 09/10/2020                  | 12/10/2020 | 16/11/2020                               | 20/11/2020              | 26/11/2020       | 26/11/2020                 | 30/11/2020              | 03/12/2020                                  | 10/12/2020                                   |
| B11 | 27/11/2020                  | 30/11/2020 | 04/01/2021                               | 08/01/2021              | 14/01/2021       | 14/01/2021                 | 18/01/2021              | 21/01/2021                                  | 28/01/2021                                   |
| B12 | 23/12/2020                  | 28/12/2020 | 01/02/2021                               | 05/02/2021              | 11/02/2021       | 11/02/2021                 | 15/02/2021              | 18/02/2021                                  | 25/02/2021                                   |
| B13 | 22/01/2021                  | 25/01/2021 | 01/03/2021                               | 05/03/2021              | 11/03/2021       | 11/03/2021                 | 15/03/2021              | 18/03/2021                                  | 25/03/2021                                   |
| B14 | 19/02/2021                  | 22/02/2021 | 29/03/2021                               | 02/04/2021              | 09/04/2021       | 09/04/2021                 | 12/04/2021              | 15/04/2021                                  | 22/04/2021                                   |
| B15 | 19/03/2021                  | 22/03/2021 | 26/04/2021                               | 30/04/2021              | 06/05/2021       | 06/05/2021                 | 10/05/2021              | 12/05/2021                                  | 20/05/2021                                   |
| B16 | 23/04/2021                  | 26/04/2021 | 31/05/2021                               | 04/06/2021              | 10/06/2021       | 10/06/2021                 | 14/06/2021              | 17/06/2021                                  | 24/06/2021                                   |
| B17 | 21/05/2021                  | 24/05/2021 | 28/06/2021                               | 02/07/2021              | 08/07/2021       | 08/07/2021                 | 12/07/2021              | 15/07/2021                                  | 22/07/2021                                   |
| B18 |                             |            |  |                         |                  |                            |                         |   |  |
| B19 | 16/07/2021                  | 19/07/2021 | 23/08/2021                               | 27/08/2021              | 03/09/2021       | 03/09/2021                 | 06/09/2021              | 09/09/2021                                  | 16/09/2021                                   |
| B20 | 13/08/2021                  | 16/08/2021 | 20/09/2021                               | 24/09/2021              | 30/09/2021       | 30/09/2021                 | 04/10/2021              | 07/10/2021                                  | 14/10/2021                                   |
| B21 | 10/09/2021                  | 13/09/2021 | 18/10/2021                               | 22/10/2021              | 28/10/2021       | 28/10/2021                 | 29/10/2021              | 04/11/2021                                  | 11/11/2021                                   |
| B22 | 15/10/2021                  | 18/10/2021 | 22/11/2021                               | 26/11/2021              | 02/12/2021       | 02/12/2021                 | 06/12/2021              | 09/12/2021                                  | 16/12/2021                                   |
| B23 | 26/11/2021                  | 29/11/2021 | 03/01/2022                               | 07/01/2022              | 13/01/2022       | 13/01/2022                 | 17/01/2022              | 20/01/2022                                  | 27/01/2022                                   |

|     | Deadline for Submission (*) | Restart    | CHMP and PRAC Rapporteurs Joint AR (JAR) | Comments from PRAC (**) | PRAC outcome (#) | Updated PRAC Rapporteur AR | Comments from CHMP (**) | Updated CHMP (and PRAC) Rapporteurs JAR (~) | List of Outstanding Issues (LoOI) or Opinion |
|-----|-----------------------------|------------|--|-------------------------|------------------|----------------------------|-------------------------|---|--|
| B24 | 22/12/2021                  | 27/12/2021 | 31/01/2022                               | 04/02/2022              | 10/02/2022       | 10/02/2022                 | 14/02/2022              | 17/02/2022                                  | 24/02/2022                                   |
| B25 | 21/01/2022                  | 24/01/2022 | 28/02/2022                               | 04/03/2022              | 10/03/2022       | 10/03/2022                 | 14/03/2022              | 17/03/2022                                  | 24/03/2022                                   |
| B26 | 18/02/2022                  | 22/02/2022 | 28/03/2022                               | 01/04/2022              | 07/04/2022       | 07/04/2022                 | 11/04/2022              | 13/04/2022                                  | 22/04/2022                                   |
| B27 | 18/03/2022                  | 21/03/2022 | 25/04/2022                               | 29/04/2022              | 05/05/2022       | 05/05/2022                 | 10/05/2022              | 12/05/2022                                  | 19/05/2022                                   |
| B28 | 22/04/2022                  | 25/04/2022 | 30/05/2022                               | 03/06/2022              | 10/06/2022       | 10/06/2022                 | 13/06/2022              | 16/06/2022                                  | 23/06/2022                                   |
| B29 | 20/05/2022                  | 23/05/2022 | 27/06/2022                               | 01/07/2022              | 07/07/2022       | 07/07/2022                 | 11/07/2022              | 14/07/2022                                  | 21/07/2022                                   |
| B30 |                             |            |  |                         |                  |                            |                         |   |  |
| B31 | 15/07/2022                  | 18/07/2022 | 22/08/2022                               | 26/08/2022              | 01/09/2022       | 01/09/2022                 | 05/09/2022              | 08/09/2022                                  | 15/09/2022                                   |
| B32 | 12/08/2022                  | 15/08/2022 | 19/09/2022                               | 23/09/2022              | 29/09/2022       | 29/09/2022                 | 03/10/2022              | 06/10/2022                                  | 13/10/2022                                   |
| B33 | 09/09/2022                  | 12/09/2022 | 17/10/2022                               | 21/10/2022              | 27/10/2022       | 27/10/2022                 | 28/10/2022              | 03/11/2022                                  | 10/11/2022                                   |
| B34 | 14/10/2022                  | 17/10/2022 | 21/11/2022                               | 25/11/2022              | 01/12/2022       | 01/12/2022                 | 05/12/2022              | 08/12/2022                                  | 15/12/2022                                   |
| B35 | 25/11/2022                  | 28/11/2022 | 03/01/2023                               | 06/01/2023              | 12/01/2023       | 12/01/2023                 | 16/01/2023              | 19/01/2023                                  | 26/01/2023                                   |
| B36 | 22/12/2022                  | 26/12/2022 | 30/01/2023                               | 03/02/2023              | 09/02/2023       | 09/02/2023                 | 13/02/2023              | 16/02/2023                                  | 23/02/2023                                   |
| B37 | 27/01/2023                  | 30/01/2023 | 06/03/2023                               | 10/03/2023              | 16/03/2023       | 16/03/2023                 | 20/03/2023              | 23/03/2023                                  | 30/03/2023                                   |
| B38 | 23/02/2023                  | 26/02/2023 | 03/04/2023                               | 05/04/2023              | 14/04/2023       | 14/04/2023                 | 17/04/2023              | 20/04/2023                                  | 26/04/2023                                   |
| B39 | 24/03/2023                  | 27/03/2023 | 02/05/2023                               | 05/05/2023              | 12/05/2023       | 12/05/2023                 | 15/05/2023              | 17/05/2023                                  | 25/05/2023                                   |
| B40 | 21/04/2023                  | 24/04/2023 | 30/05/2023                               | 02/06/2023              | 08/06/2023       | 08/06/2023                 | 12/06/2023              | 15/06/2023                                  | 22/06/2023                                   |
| B41 | 17/05/2023                  | 22/05/2023 | 26/06/2023                               | 30/06/2023              | 06/07/2023       | 06/07/2023                 | 10/07/2023              | 13/07/2023                                  | 20/07/2023                                   |
| B42 |                             |            |  |                         |                  |                            |                         |   |  |
| B43 | 14/07/2023                  | 17/07/2023 | 21/08/2023                               | 25/08/2023              | 31/08/2023       | 31/08/2023                 | 04/09/2023              | 07/09/2023                                  | 14/09/2023                                   |
| B44 | 11/08/2023                  | 14/08/2023 | 18/09/2023                               | 22/09/2023              | 28/09/2023       | 28/09/2023                 | 02/10/2023              | 05/10/2023                                  | 12/10/2023                                   |
| B45 | 08/09/2023                  | 11/09/2023 | 16/10/2023                               | 20/10/2023              | 26/10/2023       | 26/10/2023                 | 27/10/2023              | 31/10/2023                                  | 09/11/2023                                   |
| B46 | 13/10/2023                  | 16/10/2023 | 20/11/2023                               | 24/11/2023              | 30/11/2023       | 30/11/2023                 | 04/12/2023              | 07/12/2023                                  | 14/12/2023                                   |
| B47 | 24/11/2023                  | 27/11/2023 | 03/01/2024                               | 05/01/2024              | 11/01/2024       | 11/01/2024                 | 15/01/2024              | 18/01/2024                                  | 25/01/2024                                   |
| B48 | 21/12/2023                  | 25/12/2023 | 29/01/2024                               | 02/02/2024              | 08/02/2024       | 08/02/2024                 | 12/02/2024              | 15/02/2024                                  | 22/02/2024                                   |
| B49 | 19/01/2024                  | 22/01/2024 | 26/02/2024                               | 01/03/2024              | 07/03/2024       | 07/03/2024                 | 11/03/2024              | 14/03/2024                                  | 21/03/2024                                   |

|     | Deadline for Submission (*) | Restart    | CHMP and PRAC Rapporteurs Joint AR (JAR) | Comments from PRAC (**) | PRAC outcome (#) | Updated PRAC Rapporteur AR | Comments from CHMP (**) | Updated CHMP (and PRAC) Rapporteurs JAR (~) | List of Outstanding Issues (LoOI) or Opinion |
|-----|-----------------------------|------------|--|-------------------------|------------------|----------------------------|-------------------------|---|--|
| B50 | 23/02/2024                  | 26/02/2024 | 02/04/2024                               | 05/04/2024              | 11/04/2024       | 11/04/2024                 | 15/04/2024              | 18/04/2024                                  | 25/04/2024                                   |
| B51 | 27/03/2024                  | 01/04/2024 | 06/05/2024                               | 08/05/2024              | 16/05/2024       | 16/05/2024                 | 17/05/2024              | 23/05/2024                                  | 30/05/2024                                   |
| B52 | 26/04/2024                  | 29/04/2024 | 03/06/2024                               | 07/06/2024              | 13/06/2024       | 13/06/2024                 | 17/06/2024              | 20/06/2024                                  | 27/06/2024                                   |
| B53 | 24/05/2024                  | 27/05/2024 | 01/07/2024                               | 05/07/2024              | 11/07/2024       | 11/07/2024                 | 15/07/2024              | 18/07/2024                                  | 25/07/2024                                   |
| B54 |                             |            |  |                         |                  |                            |                         |   |  |
| B55 | 19/07/2024                  | 22/07/2024 | 26/08/2024                               | 30/08/2024              | 05/09/2024       | 05/09/2024                 | 09/09/2024              | 12/09/2024                                  | 19/09/2024                                   |
| B56 | 16/08/2024                  | 19/08/2024 | 23/09/2024                               | 27/09/2024              | 03/10/2024       | 03/10/2024                 | 07/10/2024              | 10/10/2024                                  | 17/10/2024                                   |
| B57 | 13/09/2024                  | 16/09/2024 | 21/10/2024                               | 25/10/2024              | 31/10/2024       | 31/10/2024                 | 04/11/2024              | 07/11/2024                                  | 14/11/2024                                   |
| B58 | 11/10/2024                  | 14/10/2024 | 18/11/2024                               | 22/11/2024              | 28/11/2024       | 28/11/2024                 | 02/12/2024              | 05/12/2024                                  | 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 CHMP and PRAC members are not made available to Applicants.

(#) The PRAC outcome is captured in the subsequent PRAC Rapporteur updated assessment report.

(~) This assessment report incorporates the PRAC Rapporteur updated assessment report circulated earlier at the conclusion of the PRAC meeting.

# Assessment of responses to List of Outstanding Issues (LoOI)

30-day timetable after clock-stop for responses

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



|     | Deadline for Submission (*) | Restart    | CHMP and PRAC Rapporteurs Joint AR (JAR) | Comments from PRAC and CHMP (**) | Updated CHMP and PRAC Rapporteurs JAR (~) | Opinion    |
|-----|-----------------------------|------------|--|----------------------------------|---|------------|
| C40 | 25/04/2023                  | 26/04/2023 | 10/05/2023                               | 15/05/2023                       | 17/05/2023                                | 25/05/2023 |
| C41 | 23/05/2023                  | 24/05/2023 | 07/06/2023                               | 12/06/2023                       | 15/06/2023                                | 22/06/2023 |
| C42 | 20/06/2023                  | 21/06/2023 | 05/07/2023                               | 10/07/2023                       | 13/07/2023                                | 20/07/2023 |
| C43 |                             |            |  |                                  |   |            |
| C44 | 14/08/2023                  | 16/08/2023 | 30/08/2023                               | 04/09/2023                       | 07/09/2023                                | 14/09/2023 |
| C45 | 12/09/2023                  | 13/09/2023 | 27/09/2023                               | 02/10/2023                       | 05/10/2023                                | 12/10/2023 |
| C46 | 10/10/2023                  | 11/10/2023 | 25/10/2023                               | 30/10/2023                       | 31/10/2023                                | 09/11/2023 |
| C47 | 14/11/2023                  | 15/11/2023 | 29/11/2023                               | 04/12/2023                       | 07/12/2023                                | 14/12/2023 |
| C48 | 21/12/2023                  | 27/12/2023 | 10/01/2024                               | 15/01/2024                       | 18/01/2024                                | 25/01/2024 |
| C49 | 23/01/2024                  | 24/01/2024 | 07/02/2024                               | 12/02/2024                       | 15/02/2024                                | 22/02/2024 |
| C50 | 20/02/2024                  | 21/02/2024 | 06/03/2024                               | 11/03/2024                       | 14/03/2024                                | 21/03/2024 |
| C51 | 26/03/2024                  | 27/03/2024 | 10/04/2024                               | 15/04/2024                       | 18/04/2024                                | 25/04/2024 |
| C52 | 30/04/2024                  | 01/05/2024 | 15/05/2024                               | 21/05/2024                       | 23/05/2024                                | 30/05/2024 |
| C53 | 28/05/2024                  | 29/05/2024 | 12/06/2024                               | 17/06/2024                       | 20/06/2024                                | 27/06/2024 |
| C54 | 25/06/2024                  | 26/06/2024 | 10/07/2024                               | 15/07/2024                       | 18/07/2024                                | 25/07/2024 |
| C55 |                             |            |  |                                  |   |            |
| C56 | 20/08/2024                  | 21/08/2024 | 04/09/2024                               | 09/09/2024                       | 12/09/2024                                | 19/09/2024 |
| C57 | 17/09/2024                  | 18/09/2024 | 02/10/2024                               | 07/10/2024                       | 10/10/2024                                | 17/10/2024 |
| C58 | 15/10/2024                  | 16/10/2024 | 30/10/2024                               | 04/11/2024                       | 07/11/2024                                | 14/11/2024 |
| C59 | 12/11/2024                  | 13/11/2024 | 27/11/2024                               | 02/12/2024                       | 05/12/2024                                | 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 CHMP and PRAC members are not made available to Applicants.

(~) A PRAC discussion is not foreseen for a 30-day timetable; PRAC member comments are reflected in the updated PRAC Rapporteur AR.

# Assessment of responses to List of Outstanding Issues (LoOI)

30-day timetable after immediate responses<sup>#</sup>

|     | Deadline for Submission (*) | Restart    | CHMP and PRAC Rapporteurs Joint AR (JAR) | Comments from PRAC and CHMP (**) | Updated CHMP and PRAC Rapporteurs JAR (~) | Opinion    |
|-----|-----------------------------|------------|--|----------------------------------|---|------------|
| D1  | 23/12/2019                  | 01/01/2020 | 15/01/2020                               | 20/01/2020                       | 23/01/2020                                | 30/01/2020 |
| D2  | 04/02/2020                  | 05/02/2020 | 12/02/2020                               | 17/02/2020                       | 20/02/2020                                | 27/02/2020 |
| D3  | 03/03/2020                  | 04/03/2020 | 11/03/2020                               | 16/03/2020                       | 19/03/2020                                | 26/03/2020 |
| D4  | 02/04/2020                  | 03/04/2020 | 15/04/2020                               | 20/04/2020                       | 23/04/2020                                | 30/04/2020 |
| D5  | 05/05/2020                  | 06/05/2020 | 13/05/2020                               | 18/05/2020                       | 20/05/2020                                | 28/05/2020 |
| D6  | 02/06/2020                  | 03/06/2020 | 10/06/2020                               | 15/06/2020                       | 18/06/2020                                | 25/06/2020 |
| D7  | 30/06/2020                  | 01/07/2020 | 08/07/2020                               | 13/07/2020                       | 16/07/2020                                | 23/07/2020 |
| D8  |                             |            |  |                                  |   |            |
| D9  | 25/08/2020                  | 26/08/2020 | 02/09/2020                               | 07/09/2020                       | 10/09/2020                                | 17/09/2020 |
| D10 | 22/09/2020                  | 23/09/2020 | 30/09/2020                               | 05/10/2020                       | 08/10/2020                                | 15/10/2020 |
| D11 | 20/10/2020                  | 21/10/2020 | 28/10/2020                               | 03/11/2020                       | 05/11/2020                                | 12/11/2020 |
| D12 | 17/11/2020                  | 18/11/2020 | 25/11/2020                               | 30/11/2020                       | 03/12/2020                                | 10/12/2020 |
| D13 | 23/12/2020                  | 30/12/2020 | 13/01/2021                               | 18/01/2021                       | 21/01/2021                                | 28/01/2021 |
| D14 | 02/02/2021                  | 03/02/2021 | 10/02/2021                               | 15/02/2021                       | 18/02/2021                                | 25/02/2021 |
| D15 | 02/03/2021                  | 03/03/2021 | 10/03/2021                               | 15/03/2021                       | 18/03/2021                                | 25/03/2021 |
| D16 | 30/03/2021                  | 31/03/2021 | 07/04/2021                               | 12/04/2021                       | 15/04/2021                                | 22/04/2021 |
| D17 | 27/04/2021                  | 28/04/2021 | 05/05/2021                               | 10/05/2021                       | 12/05/2021                                | 20/05/2021 |
| D18 | 27/05/2021                  | 28/05/2021 | 09/06/2021                               | 14/06/2021                       | 17/06/2021                                | 24/06/2021 |
| D19 | 29/06/2021                  | 30/06/2021 | 07/07/2021                               | 12/07/2021                       | 15/07/2021                                | 22/07/2021 |
| D20 |                             |            |  |                                  |   |            |
| D21 | 24/08/2021                  | 25/08/2021 | 01/09/2021                               | 06/09/2021                       | 09/09/2021                                | 16/09/2021 |
| D22 | 21/09/2021                  | 22/09/2021 | 29/09/2021                               | 04/10/2021                       | 07/10/2021                                | 14/10/2021 |
| D23 | 19/10/2021                  | 20/10/2021 | 27/10/2021                               | 03/11/2021                       | 05/11/2021                                | 11/11/2021 |
| D24 | 18/11/2021                  | 19/11/2021 | 01/12/2021                               | 06/12/2021                       | 09/12/2021                                | 16/12/2021 |
| D25 | 22/12/2021                  | 29/12/2021 | 12/01/2022                               | 17/01/2022                       | 20/01/2022                                | 27/01/2022 |
| D26 | 01/02/2022                  | 02/02/2022 | 09/02/2022                               | 14/02/2022                       | 17/02/2022                                | 24/02/2022 |
| D27 | 01/03/2022                  | 02/03/2022 | 09/03/2022                               | 14/03/2022                       | 17/03/2022                                | 24/03/2022 |
| D28 | 30/03/2022                  | 31/03/2022 | 06/04/2022                               | 11/04/2022                       | 13/04/2022                                | 22/04/2022 |
| D29 | 26/04/2022                  | 27/04/2022 | 04/05/2022                               | 10/05/2022                       | 12/05/2022                                | 19/05/2022 |
| D30 | 25/05/2022                  | 27/05/2022 | 08/06/2022                               | 13/06/2022                       | 16/06/2022                                | 23/06/2022 |
| D31 | 28/06/2022                  | 29/06/2022 | 06/07/2022                               | 11/07/2022                       | 14/07/2022                                | 21/07/2022 |
| D32 |                             |            |  |                                  |   |            |
| D33 | 16/08/2022                  | 17/08/2022 | 31/08/2022                               | 05/09/2022                       | 08/09/2022                                | 15/09/2022 |
| D34 | 20/09/2022                  | 21/09/2022 | 28/09/2022                               | 03/10/2022                       | 06/10/2022                                | 13/10/2022 |
| D35 | 18/10/2022                  | 19/10/2022 | 26/10/2022                               | 28/10/2022                       | 03/11/2022                                | 10/11/2022 |
| D36 | 16/11/2022                  | 18/11/2022 | 30/11/2022                               | 05/12/2022                       | 08/12/2022                                | 15/12/2022 |
| D37 | 22/12/2022                  | 28/12/2022 | 11/01/2023                               | 16/01/2023                       | 19/01/2023                                | 26/01/2023 |
| D38 | 31/01/2023                  | 01/02/2023 | 08/02/2023                               | 13/02/2023                       | 16/02/2023                                | 23/02/2023 |
| D39 | 28/02/2023                  | 01/03/2023 | 15/03/2023                               | 20/03/2023                       | 23/03/2023                                | 30/03/2023 |

|     | Deadline for Submission (*) | Restart    | CHMP and PRAC Rapporteurs Joint AR (JAR) | Comments from PRAC and CHMP (**) | Updated CHMP and PRAC Rapporteurs JAR (~) | Opinion    |
|-----|-----------------------------|------------|--|----------------------------------|---|------------|
| D40 | 03/04/2023                  | 04/04/2023 | 12/04/2023                               | 17/04/2023                       | 20/04/2023                                | 26/04/2023 |
| D41 | 02/05/2023                  | 03/05/2023 | 10/05/2023                               | 15/05/2023                       | 17/05/2023                                | 25/05/2023 |
| D42 | 30/05/2023                  | 31/05/2023 | 07/06/2023                               | 12/06/2023                       | 15/06/2023                                | 22/06/2023 |
| D43 | 27/06/2023                  | 28/06/2023 | 05/07/2023                               | 10/07/2023                       | 13/07/2023                                | 20/07/2023 |
| D44 |                             |            |  |                                  |   |            |
| D45 | 14/08/2023                  | 16/08/2023 | 30/08/2023                               | 04/09/2023                       | 07/09/2023                                | 14/09/2023 |
| D46 | 19/09/2023                  | 20/09/2023 | 27/09/2023                               | 02/10/2023                       | 05/10/2023                                | 12/10/2023 |
| D47 | 17/10/2023                  | 18/10/2023 | 25/10/2023                               | 30/10/2023                       | 31/10/2023                                | 09/11/2023 |
| D48 | 16/11/2023                  | 17/11/2023 | 29/11/2023                               | 04/12/2023                       | 07/12/2023                                | 14/12/2023 |
| D49 | 21/12/2023                  | 27/12/2023 | 10/01/2024                               | 15/01/2024                       | 18/01/2024                                | 25/01/2024 |
| D50 | 30/01/2024                  | 31/01/2024 | 07/02/2024                               | 12/02/2024                       | 15/02/2024                                | 22/02/2024 |
| D51 | 27/02/2024                  | 28/02/2024 | 06/03/2024                               | 11/03/2024                       | 14/03/2024                                | 21/03/2024 |
| D52 | 27/03/2024                  | 29/03/2024 | 10/04/2024                               | 15/04/2024                       | 18/04/2024                                | 25/04/2024 |
| D53 | 02/05/2024                  | 03/05/2024 | 15/05/2024                               | 21/05/2024                       | 23/05/2024                                | 30/05/2024 |
| D54 | 04/06/2024                  | 05/06/2024 | 12/06/2024                               | 17/06/2024                       | 20/06/2024                                | 27/06/2024 |
| D55 | 02/07/2024                  | 03/07/2024 | 10/07/2024                               | 15/07/2024                       | 18/07/2024                                | 25/07/2024 |
| D56 |                             |            |  |                                  |   |            |
| D57 | 20/08/2024                  | 21/08/2024 | 04/09/2024                               | 09/09/2024                       | 12/09/2024                                | 19/09/2024 |
| D58 | 24/09/2024                  | 25/09/2024 | 02/10/2024                               | 07/10/2024                       | 10/10/2024                                | 17/10/2024 |
| D59 | 22/10/2024                  | 23/10/2024 | 30/10/2024                               | 04/11/2024                       | 07/11/2024                                | 14/11/2024 |
| D60 | 19/11/2024                  | 20/11/2024 | 27/11/2024                               | 02/12/2024                       | 05/12/2024                                | 12/12/2024 |

(#) This timetable is only used exceptionally and after agreement with the Rapporteurs when minor issues remain which allow the applicant to respond shortly after the CHMP list of questions and the Rapporteurs to assess the responses within a shortened assessment time.

(\*) 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 and PRAC members are not made available to Applicants.

(~) A PRAC discussion is not foreseen for a 30-day timetable; PRAC member comments are reflected in the updated PRAC Rapporteur AR.

# Assessment of Outstanding Issues following Oral Explanation

30-day timetable<sup>#</sup>

|     | Restart    | (PRAC and) CHMP<br>Rapporteurs Joint<br>AR (JAR) (*) | Comments from<br>(PRAC and) CHMP<br>on JAR (**) | Updated (PRAC<br>and) CHMP<br>Rapporteurs JAR | Opinion    |
|-----|------------|--|---|---|------------|
| E1  | 08/01/2020 | 15/01/2020   | 20/01/2020                                      | 23/01/2020                                    | 30/01/2020 |
| E2  | 05/02/2020 | 12/02/2020   | 17/02/2020                                      | 20/02/2020                                    | 27/02/2020 |
| E3  | 04/03/2020 | 11/03/2020   | 16/03/2020                                      | 19/03/2020                                    | 26/03/2020 |
| E4  | 08/04/2020 | 15/04/2020   | 20/04/2020                                      | 23/04/2020                                    | 30/04/2020 |
| E5  | 06/05/2020 | 13/05/2020   | 18/05/2020                                      | 20/05/2020                                    | 28/05/2020 |
| E6  | 03/06/2020 | 10/06/2020   | 15/06/2020                                      | 18/06/2020                                    | 25/06/2020 |
| E7  | 01/07/2020 | 08/07/2020   | 13/07/2020                                      | 16/07/2020                                    | 23/07/2020 |
| E8  |            |  |   |   |            |
| E9  | 26/08/2020 | 02/09/2020   | 07/09/2020                                      | 10/09/2020                                    | 17/09/2020 |
| E10 | 23/09/2020 | 30/09/2020   | 05/10/2020                                      | 08/10/2020                                    | 15/10/2020 |
| E11 | 21/10/2020 | 28/10/2020   | 03/11/2020                                      | 05/11/2020                                    | 12/11/2020 |
| E12 | 18/11/2020 | 25/11/2020   | 30/11/2020                                      | 03/12/2020                                    | 10/12/2020 |
| E13 | 06/01/2021 | 13/01/2021   | 18/01/2021                                      | 21/01/2021                                    | 28/01/2021 |
| E14 | 03/02/2021 | 10/02/2021   | 15/02/2021                                      | 18/02/2021                                    | 25/02/2021 |
| E15 | 03/03/2021 | 10/03/2021   | 15/03/2021                                      | 18/03/2021                                    | 25/03/2021 |
| E16 | 31/03/2021 | 07/04/2021   | 12/04/2021                                      | 15/04/2021                                    | 22/04/2021 |
| E17 | 28/04/2021 | 05/05/2021   | 10/05/2021                                      | 12/05/2021                                    | 20/05/2021 |
| E18 | 02/06/2021 | 09/06/2021   | 14/06/2021                                      | 17/06/2021                                    | 24/06/2021 |
| E19 | 30/06/2021 | 07/07/2021   | 12/07/2021                                      | 15/07/2021                                    | 22/07/2021 |
| E20 |            |  |   |   |            |
| E21 | 25/08/2021 | 01/09/2021   | 06/09/2021                                      | 09/09/2021                                    | 16/09/2021 |
| E22 | 22/09/2021 | 29/09/2021   | 04/10/2021                                      | 07/10/2021                                    | 14/10/2021 |
| E23 | 20/10/2021 | 27/10/2021   | 03/11/2021                                      | 05/11/2021                                    | 11/11/2021 |
| E24 | 24/11/2021 | 01/12/2021   | 06/12/2021                                      | 09/12/2021                                    | 16/12/2021 |
| E25 | 29/12/2021 | 12/01/2022   | 17/01/2022                                      | 20/01/2022                                    | 27/01/2022 |
| E26 | 02/02/2022 | 09/02/2022   | 14/02/2022                                      | 17/02/2022                                    | 24/02/2022 |
| E27 | 02/03/2022 | 09/03/2022   | 14/03/2022                                      | 17/03/2022                                    | 24/03/2022 |
| E28 | 31/03/2022 | 06/04/2022   | 11/04/2022                                      | 13/04/2022                                    | 22/04/2022 |
| E29 | 27/04/2022 | 04/05/2022   | 10/05/2022                                      | 12/05/2022                                    | 19/05/2022 |
| E30 | 27/05/2022 | 08/06/2022   | 13/06/2022                                      | 16/06/2022                                    | 23/06/2022 |
| E31 | 29/06/2022 | 06/07/2022   | 11/07/2022                                      | 14/07/2022                                    | 21/07/2022 |
| E32 |            |  |   |   |            |
| E33 | 17/08/2022 | 31/08/2022   | 05/09/2022                                      | 08/09/2022                                    | 15/09/2022 |
| E34 | 21/09/2022 | 28/09/2022   | 03/10/2022                                      | 06/10/2022                                    | 13/10/2022 |
| E35 | 19/10/2022 | 26/10/2022   | 28/10/2022                                      | 03/11/2022                                    | 10/11/2022 |
| E36 | 18/11/2022 | 30/11/2022   | 05/12/2022                                      | 08/12/2022                                    | 15/12/2022 |
| E37 | 28/12/2022 | 11/01/2023   | 16/01/2023                                      | 19/01/2023                                    | 26/01/2023 |
| E38 | 01/02/2023 | 08/02/2023   | 13/02/2023                                      | 16/02/2023                                    | 23/02/2023 |
| E39 | 01/03/2023 | 15/03/2023   | 20/03/2023                                      | 23/03/2023                                    | 30/03/2023 |

|     | Restart    | (PRAC and) CHMP Rapporteurs Joint AR (JAR) (*) | Comments from (PRAC and) CHMP on JAR (**) | Updated (PRAC and) CHMP Rapporteurs JAR | Opinion    |
|-----|------------|--|---|---|------------|
| E40 | 04/04/2023 | 12/04/2023                                     | 17/04/2023                                | 20/04/2023                              | 26/04/2023 |
| E41 | 03/05/2023 | 10/05/2023                                     | 15/05/2023                                | 17/05/2023                              | 25/05/2023 |
| E42 | 31/05/2023 | 07/06/2023                                     | 12/06/2023                                | 15/06/2023                              | 22/06/2023 |
| E43 | 28/06/2023 | 05/07/2023                                     | 10/07/2023                                | 13/07/2023                              | 20/07/2023 |
| E44 |            |  |   |   |            |
| E45 | 16/08/2023 | 30/08/2023                                     | 04/09/2023                                | 07/09/2023                              | 14/09/2023 |
| E46 | 20/09/2023 | 27/09/2023                                     | 02/10/2023                                | 05/10/2023                              | 12/10/2023 |
| E47 | 18/10/2023 | 25/10/2023                                     | 30/10/2023                                | 31/10/2023                              | 09/11/2023 |
| E48 | 17/11/2023 | 29/11/2023                                     | 04/12/2023                                | 07/12/2023                              | 14/12/2023 |
| E49 | 27/12/2023 | 10/01/2024                                     | 15/01/2024                                | 18/01/2024                              | 25/01/2024 |
| E50 | 31/01/2024 | 07/02/2024                                     | 12/02/2024                                | 15/02/2024                              | 22/02/2024 |
| E51 | 28/02/2024 | 06/03/2024                                     | 11/03/2024                                | 14/03/2024                              | 21/03/2024 |
| E52 | 29/03/2024 | 10/04/2024                                     | 15/04/2024                                | 18/04/2024                              | 25/04/2024 |
| E53 | 03/05/2024 | 15/05/2024                                     | 21/05/2024                                | 23/05/2024                              | 30/05/2024 |
| E54 | 05/06/2024 | 12/06/2024                                     | 17/06/2024                                | 20/06/2024                              | 27/06/2024 |
| E55 | 03/07/2024 | 10/07/2024                                     | 15/07/2024                                | 18/07/2024                              | 25/07/2024 |
| E56 |            |  |   |   |            |
| E57 | 21/08/2024 | 04/09/2024                                     | 09/09/2024                                | 12/09/2024                              | 19/09/2024 |
| E58 | 25/09/2024 | 02/10/2024                                     | 07/10/2024                                | 10/10/2024                              | 17/10/2024 |
| E59 | 23/10/2024 | 30/10/2024                                     | 04/11/2024                                | 07/11/2024                              | 14/11/2024 |
| E60 | 20/11/2024 | 27/11/2024                                     | 02/12/2024                                | 05/12/2024                              | 12/12/2024 |

(#) This timetable is used when minor issues, most commonly but not exclusively related to the Product Information and the Risk Management Plan, remain after an Oral Explanation.

(\*) The involvement of CHMP and PRAC Rapporteurs in this assessment phase depends on the nature of the remaining issues and it could be optional for the PRAC Rapporteur.

(\*\*) Comments from CHMP (and PRAC, if applicable) members are not made available to Applicants.