



11 September 2024  
EMA/251636/2015 Rev.10  
Human Medicines Division

The timetables in this document may be subject to revision

## Periodic Safety Update Report (PSUR)/PSUR Single Assessment (PSUSA)

|     | PSUR/PSUSA cut off date(*) | Start date | PRAC Rapporteur AR | Comments from PRAC/MAH (**) | Updated PRAC Rapporteur AR (***) | PRAC Recommendation | CHMP/CMD(h) members comments (**) (^) | CHMP Opinion/CMD(h) position (^) |
|-----|----------------------------|------------|--------------------|-----------------------------|----------------------------------|---------------------|---------------------------------------|----------------------------------|
| A1  | 08/09/2022                 | 15/09/2022 | 14/11/2022         | 14/12/2022                  | 29/12/2022                       | 12/01/2023          | 19/01/2023                            | 26/01/2023                       |
| A2  | 06/10/2022                 | 13/10/2022 | 12/12/2022         | 11/01/2023                  | 26/01/2023                       | 09/02/2023          | 16/02/2023                            | 23/02/2023                       |
| A3  | 10/11/2022                 | 17/11/2022 | 16/01/2023         | 15/02/2023                  | 02/03/2023                       | 16/03/2023          | 23/03/2023                            | 30/03/2023                       |
| A4  | 09/12/2022                 | 16/12/2022 | 14/02/2023         | 16/03/2023                  | 31/03/2023                       | 14/04/2023          | 19/04/2023                            | 26/04/2023                       |
| A5  | 06/01/2023                 | 13/01/2023 | 14/03/2023         | 13/04/2023                  | 28/04/2023                       | 12/05/2023          | 17/05/2023                            | 25/05/2023                       |
| A6  | 02/02/2023                 | 09/02/2023 | 10/04/2023         | 10/05/2023                  | 25/05/2023                       | 08/06/2023          | 15/06/2023                            | 22/06/2023                       |
| A7  | 08/03/2023                 | 09/03/2023 | 08/05/2023         | 07/06/2023                  | 22/06/2023                       | 06/07/2023          | 13/07/2023                            | 20/07/2023                       |
| A8  |                            |            |                    |                             |                                  |                     |                                       |                                  |
| A9  | 20/04/2023                 | 04/05/2023 | 03/07/2023         | 02/08/2023                  | 17/08/2023                       | 31/08/2023          | 07/09/2023                            | 14/09/2023                       |
| A10 | 25/05/2023                 | 01/06/2023 | 31/07/2023         | 30/08/2023                  | 14/09/2023                       | 28/09/2023          | 05/10/2023                            | 12/10/2023                       |
| A11 | 22/06/2023                 | 29/06/2023 | 28/08/2023         | 27/09/2023                  | 12/10/2023                       | 26/10/2023          | 31/10/2023                            | 09/11/2023                       |
| A12 | 27/07/2023                 | 03/08/2023 | 02/10/2023         | 01/11/2023                  | 16/11/2023                       | 30/11/2023          | 07/12/2023                            | 14/12/2023                       |
| A13 | 07/09/2023                 | 14/09/2023 | 13/11/2023         | 13/12/2023                  | 28/12/2023                       | 11/01/2024          | 18/01/2024                            | 25/01/2024                       |
| A14 | 05/10/2023                 | 12/10/2023 | 11/12/2023         | 10/01/2024                  | 25/01/2024                       | 08/02/2024          | 15/02/2024                            | 22/02/2024                       |
| A15 | 31/10/2023                 | 09/11/2023 | 08/01/2024         | 07/02/2024                  | 22/02/2024                       | 07/03/2024          | 14/03/2024                            | 21/03/2024                       |
| A16 | 07/12/2023                 | 14/12/2023 | 12/02/2024         | 13/03/2024                  | 28/03/2024                       | 11/04/2024          | 18/04/2024                            | 25/04/2024                       |

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|-----|----------------------------------|------------|--------------------------|--------------------------------------|-------------------------------------------|--------------------------|------------------------------------------------|-----------------------------------------|
| A17 | 11/01/2024                       | 18/01/2024 | 18/03/2024               | 17/04/2024                           | 02/05/2024                                | 16/05/2024               | 23/05/2024                                     | 30/05/2024                              |
| A18 | 08/02/2024                       | 15/02/2024 | 15/04/2024               | 15/05/2024                           | 30/05/2024                                | 13/06/2024               | 20/06/2024                                     | 27/06/2024                              |
| A19 | 13/03/2024                       | 14/03/2024 | 13/05/2024               | 12/06/2024                           | 27/06/2024                                | 11/07/2024               | 18/07/2024                                     | 25/07/2024                              |
| A20 |                                  |            |                          |                                      |                                           |                          |                                                |                                         |
| A21 | 25/04/2024                       | 09/05/2024 | 08/07/2024               | 07/08/2024                           | 22/08/2024                                | 05/09/2024               | 12/09/2024                                     | 19/09/2024                              |
| A22 | 30/05/2024                       | 06/06/2024 | 05/08/2024               | 04/09/2024                           | 19/09/2024                                | 03/10/2024               | 10/10/2024                                     | 17/10/2024                              |
| A23 | 27/06/2024                       | 04/07/2024 | 02/09/2024               | 02/10/2024                           | 17/10/2024                                | 31/10/2024               | 07/11/2024                                     | 14/11/2024                              |
| A24 | 25/07/2024                       | 01/08/2024 | 30/09/2024               | 30/10/2024                           | 14/11/2024                                | 28/11/2024               | 05/12/2024                                     | 12/12/2024                              |
| A25 | 12/09/2024                       | 19/09/2024 | 18/11/2024               | 18/12/2024                           | 06/01/2025                                | 16/01/2025               | 23/01/2025                                     | 30/01/2025                              |
| A26 | 10/10/2024                       | 17/10/2024 | 16/12/2024               | 15/01/2025                           | 30/01/2025                                | 13/02/2025               | 20/02/2025                                     | 27/02/2025                              |
| A27 | 07/11/2024                       | 14/11/2024 | 13/01/2025               | 12/02/2025                           | 27/02/2025                                | 13/03/2025               | 20/03/2025                                     | 27/03/2025                              |
| A28 | 05/12/2024                       | 12/12/2024 | 10/02/2025               | 12/03/2025                           | 27/03/2025                                | 10/04/2025               | 17/04/2025                                     | 25/04/2025                              |
| A29 | 02/01/2025                       | 09/01/2025 | 10/03/2025               | 09/04/2025                           | 24/04/2025                                | 08/05/2025               | 15/05/2025                                     | 22/05/2025                              |
| A30 | 30/01/2025                       | 06/02/2025 | 07/04/2025               | 07/05/2025                           | 22/05/2025                                | 05/06/2025               | 12/06/2025                                     | 19/06/2025                              |
| A31 | 12/03/2025                       | 13/03/2025 | 12/05/2025               | 11/06/2025                           | 26/06/2025                                | 10/07/2025               | 17/07/2025                                     | 24/07/2025                              |
| A32 | 24/04/2025                       | 08/05/2025 | 07/07/2025               | 06/08/2025                           | 21/08/2025                                | 04/09/2025               | 11/09/2025                                     | 18/09/2025                              |
| A33 | 28/05/2025                       | 05/06/2025 | 04/08/2025               | 03/09/2025                           | 18/09/2025                                | 02/10/2025               | 09/10/2025                                     | 16/10/2025                              |
| A34 | 26/06/2025                       | 03/07/2025 | 01/09/2025               | 01/10/2025                           | 16/10/2025                                | 30/10/2025               | 06/11/2025                                     | 13/11/2025                              |
| A35 | 24/07/2025                       | 31/07/2025 | 29/09/2025               | 29/10/2025                           | 13/11/2025                                | 27/11/2025               | 04/12/2025                                     | 11/12/2025                              |
| A36 | 11/09/2025                       | 18/09/2025 | 17/11/2025               | 17/12/2025                           | 01/01/2026                                | 15/01/2026               | 22/01/2026                                     | 29/01/2026                              |
| A37 | 09/10/2025                       | 16/10/2025 | 15/12/2025               | 14/01/2026                           | 29/01/2026                                | 12/02/2026               | 19/02/2026                                     | 26/02/2026                              |
| A38 | 06/11/2025                       | 13/11/2025 | 12/01/2026               | 11/02/2026                           | 26/02/2026                                | 12/03/2026               | 19/03/2026                                     | 26/03/2026                              |
| A39 | 05/12/2025                       | 12/12/2025 | 10/02/2026               | 12/03/2026                           | 27/03/2026                                | 10/04/2026               | 17/04/2026                                     | 23/04/2026                              |
| A40 | 23/12/2025                       | 08/01/2026 | 09/03/2026               | 08/04/2026                           | 23/04/2026                                | 07/05/2026               | 14/05/2026                                     | 21/05/2026                              |
| A41 | 05/02/2026                       | 12/02/2026 | 13/04/2026               | 13/05/2026                           | 28/05/2026                                | 11/06/2026               | 18/06/2026                                     | 25/06/2026                              |
| A42 | 11/03/2026                       | 12/03/2026 | 11/05/2026               | 10/06/2026                           | 25/06/2026                                | 09/07/2026               | 16/07/2026                                     | 23/07/2026                              |

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|-----|----------------------------------|------------|--------------------------|--------------------------------------|-------------------------------------------|--------------------------|------------------------------------------------|-----------------------------------------|
| A43 | 23/04/2026                       | 07/05/2026 | 06/07/2026               | 05/08/2026                           | 20/08/2026                                | 03/09/2026               | 10/09/2026                                     | 17/09/2026                              |
| A44 | 28/05/2026                       | 04/06/2026 | 03/08/2026               | 02/09/2026                           | 17/09/2026                                | 01/10/2026               | 08/10/2026                                     | 15/10/2026                              |
| A45 | 25/06/2026                       | 02/07/2026 | 31/08/2026               | 30/09/2026                           | 15/10/2026                                | 29/10/2026               | 05/11/2026                                     | 12/11/2026                              |
| A46 | 23/07/2026                       | 30/07/2026 | 28/09/2026               | 28/10/2026                           | 12/11/2026                                | 26/11/2026               | 03/12/2026                                     | 10/12/2026                              |

(\*) The period between PSUR/PSUSA cut-off date and start date is established to allow Marketing Authorisation Holders (MAHs) resolution of any technical issues ahead of the planned procedure start, as well as administrative processing of starting PSUR/PSUSAs by the Agency. In order to manage the missing April start date, the cut-off periods for March and May starts are adapted.

The Agency strongly recommends submitting the application before the legally binding submission deadline as stated in the List of Union reference dates (EURD list). 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, CHMP or CMDh members are not made available to Marketing Authorisation Holders (MAHs).

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

(^) This CHMP/CMDh step applies only in case of PRAC recommendation for variation to the terms of marketing authorisation.