



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

	PSUR/PSUSA cut off date(*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH (**)	Updated PRAC Rapporteur AR (***)	PRAC Recom- mendation	CHMP/CMD(h) members comments (**) (^)	CHMP Opinion/ CMD(h) position (^)
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.