



The timetables in this document may be subject to revision

Safety Signal - Assessment of responses to Request for Supplementary Information (RSI) - ATMP

[30-day](#)

[60-day](#)

[90-day](#)

30-day assessment timetable⁷

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CAT opinion (^)	CHMP adoption (^)
A1	08/12/2023	13/12/2023	03/01/2024	04/01/2024	05/01/2024	11/01/2024	19/01/2024	25/01/2024
A2	05/01/2024	10/01/2024	24/01/2024	29/01/2024	01/02/2024	08/02/2024	16/02/2024	22/02/2024
A3	02/02/2024	07/02/2024	21/02/2024	26/02/2024	29/02/2024	07/03/2024	15/03/2024	21/03/2024
A4	08/03/2024	13/03/2024	27/03/2024	02/04/2024	04/04/2024	11/04/2024	19/04/2024	25/04/2024
A5	12/04/2024	17/04/2024	02/05/2024	06/05/2024	08/05/2024	16/05/2024	24/05/2024	30/05/2024
A6	08/05/2024	15/05/2024	29/05/2024	03/06/2024	06/06/2024	13/06/2024	21/06/2024	27/06/2024
A7	07/06/2024	12/06/2024	26/06/2024	01/07/2024	04/07/2024	11/07/2024	19/07/2024	25/07/2024
A8								
A9	02/08/2024	07/08/2024	21/08/2024	26/08/2024	29/08/2024	05/09/2024	13/09/2024	19/09/2024
A10	30/08/2024	04/09/2024	18/09/2024	23/09/2024	26/09/2024	03/10/2024	11/10/2024	17/10/2024
A11	27/09/2024	02/10/2024	16/10/2024	21/10/2024	24/10/2024	31/10/2024	08/11/2024	14/11/2024
A12	25/10/2024	30/10/2024	13/11/2024	18/11/2024	21/11/2024	28/11/2024	06/12/2024	12/12/2024
A13	28/11/2024	03/12/2024	17/12/2024	06/01/2025	09/01/2025	16/01/2025	24/01/2025	30/01/2025
A14	10/01/2025	15/01/2025	29/01/2025	03/02/2025	06/02/2025	13/02/2025	21/02/2025	27/02/2025
A15	07/02/2025	12/02/2025	26/02/2025	03/03/2025	06/03/2025	13/03/2025	21/03/2025	27/03/2025
A16	07/03/2025	12/03/2025	26/03/2025	31/03/2025	03/04/2025	10/04/2025	16/04/2025	25/04/2025
A17	04/04/2025	09/04/2025	23/04/2025	28/04/2025	02/05/2025	08/05/2025	16/05/2025	22/05/2025
A18	02/05/2025	07/05/2025	21/05/2025	26/05/2025	28/05/2025	05/06/2025	13/06/2025	19/06/2025
A19	06/06/2025	11/06/2025	25/06/2025	30/06/2025	03/07/2025	10/07/2025	18/07/2025	24/07/2025
A20								
A21	18/07/2025	23/07/2025	18/08/2025	25/08/2025	28/08/2025	04/09/2025	12/10/2025	18/09/2025
A22	29/08/2025	03/09/2025	17/09/2025	22/09/2025	25/09/2025	02/10/2025	10/10/2025	16/10/2025
A23	26/09/2025	01/10/2025	15/10/2025	20/10/2025	23/10/2025	30/10/2025	07/11/2025	13/11/2025
A24	24/10/2025	29/10/2025	12/11/2025	17/11/2025	20/11/2025	27/11/2025	05/12/2025	11/12/2025
A25	05/12/2025	10/12/2025	05/01/2026	08/01/2026	12/01/2026	15/01/2026	23/01/2026	29/01/2026
A26	09/01/2026	14/01/2026	28/01/2026	02/02/2026	05/02/2026	12/02/2026	20/02/2026	26/02/2026
A27	06/02/2026	11/02/2026	25/02/2026	02/03/2026	05/03/2026	12/03/2026	20/03/2026	26/03/2026
A28	06/03/2026	12/03/2026	25/03/2026	30/03/2026	01/04/2026	10/04/2026	17/04/2026	23/04/2026
A29	01/04/2026	08/04/2026	22/04/2026	28/04/2026	30/04/2026	07/05/2026	13/05/2026	21/05/2026
A30	08/05/2026	13/05/2026	27/05/2026	01/06/2026	04/06/2026	11/06/2026	19/06/2026	25/06/2026
A31	05/06/2026	10/06/2026	24/06/2026	29/06/2026	02/07/2026	09/07/2026	17/07/2026	23/07/2026
A32								
A33	17/07/2026	22/07/2026	19/08/2026	24/08/2026	27/08/2026	03/09/2026	11/09/2026	17/09/2026
A34	28/08/2026	02/09/2026	16/09/2026	21/09/2026	24/09/2026	01/10/2026	09/10/2026	15/10/2026
A35	25/09/2026	30/09/2026	14/10/2026	19/10/2026	22/10/2026	29/10/2026	06/11/2026	12/11/2026
A36	23/10/2026	28/10/2026	11/11/2026	16/11/2026	19/11/2026	26/11/2026	04/12/2026	10/12/2026

(*) 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.

(#) An updated AR is optional and dependent on the comments received from PRAC members and Marketing Authorisation Holders (MAHs) which create the need for the update.

(^) This CAT opinion / CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of ma authorisation.

60-day assessment timetable⁷

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CAT opinion (^)	CHMP adoption (^)
B1	08/11/2023	13/11/2023	18/12/2023	03/01/2024	05/01/2024	11/01/2024	19/01/2024	25/01/2024
B2	06/12/2023	11/12/2023	15/01/2024	29/01/2024	01/02/2024	08/02/2024	16/02/2024	22/02/2024
B3	03/01/2024	08/01/2024	12/02/2024	26/02/2024	29/02/2024	07/03/2024	15/03/2024	21/03/2024
B4	07/02/2024	12/02/2024	18/03/2024	02/04/2024	04/04/2024	11/04/2024	19/04/2024	25/04/2024
B5	13/03/2024	18/03/2024	22/04/2024	06/05/2024	08/05/2024	16/05/2024	24/05/2024	30/05/2024
B6	10/04/2024	15/04/2024	21/05/2024	03/06/2024	06/06/2024	13/06/2024	21/06/2024	27/06/2024
B7	08/05/2024	13/05/2024	17/06/2024	01/07/2024	04/07/2024	11/07/2024	19/07/2024	25/07/2024
B8								
B9	03/07/2024	08/07/2024	12/08/2024	26/08/2024	29/08/2024	05/09/2024	13/09/2024	19/09/2024
B10	31/07/2024	05/08/2024	09/09/2024	23/09/2024	26/09/2024	03/10/2024	11/10/2024	17/10/2024
B11	28/08/2024	02/09/2024	07/10/2024	21/10/2024	24/10/2024	31/10/2024	08/11/2024	14/11/2024
B12	25/09/2024	30/09/2024	04/11/2024	18/11/2024	21/11/2024	28/11/2024	06/12/2024	12/12/2024
B13	30/10/2024	04/11/2024	09/12/2024	19/12/2024	09/01/2025	16/01/2025	24/01/2025	30/01/2025
B14	05/12/2024	10/12/2024	20/01/2025	03/02/2025	06/02/2025	13/02/2025	21/02/2025	27/02/2025
B15	08/01/2025	13/01/2025	17/02/2025	03/03/2025	06/03/2025	13/03/2025	21/03/2025	27/03/2025
B16	05/02/2025	10/02/2025	17/03/2025	31/03/2025	03/04/2025	10/04/2025	16/04/2025	25/04/2025
B17	05/03/2025	10/03/2025	14/04/2025	28/04/2025	02/05/2025	08/05/2025	16/05/2025	22/05/2025
B18	02/04/2025	07/04/2025	12/05/2025	26/05/2025	28/05/2025	05/06/2025	13/06/2025	19/06/2025
B19	07/05/2025	12/05/2025	16/06/2025	30/06/2025	03/07/2025	10/07/2025	18/07/2025	24/07/2025
B20								
B21	27/06/2025	02/07/2025	11/08/2025	25/08/2025	28/08/2025	04/09/2025	12/10/2025	18/09/2025
B22	23/07/2025	28/07/2025	08/09/2025	22/09/2025	25/09/2025	02/10/2025	10/10/2025	16/10/2025
B23	27/08/2025	01/09/2025	06/10/2025	20/10/2025	23/10/2025	30/10/2025	07/11/2025	13/11/2025
B24	24/09/2025	29/09/2025	03/11/2025	17/11/2025	20/11/2025	27/11/2025	05/12/2025	11/12/2025
B25	03/11/2025	10/11/2025	05/12/2025	19/12/2025	08/01/2026	15/01/2026	23/01/2026	29/01/2026
B26	10/12/2025	15/12/2025	19/01/2026	02/02/2026	05/02/2026	12/02/2026	20/02/2026	26/02/2026
B27	23/12/2025	06/01/2026	16/02/2026	02/03/2026	05/03/2026	12/03/2026	20/03/2026	26/03/2026
B28	05/02/2026	10/02/2026	16/03/2026	30/03/2026	01/04/2026	10/04/2026	17/04/2026	23/04/2026
B29	04/03/2026	09/03/2026	13/04/2026	28/04/2026	30/04/2026	07/05/2026	13/05/2026	21/05/2026
B30	08/04/2026	13/04/2026	18/05/2026	01/06/2026	04/06/2026	11/06/2026	19/06/2026	25/06/2026
B31	06/05/2026	11/05/2026	15/06/2026	29/06/2026	02/07/2026	09/07/2026	17/07/2026	23/07/2026
B32								
B33	24/06/2026	29/06/2026	06/08/2026	24/08/2026	27/08/2026	03/09/2026	11/09/2026	17/09/2026
B34	29/07/2026	03/08/2026	07/09/2026	21/09/2026	24/09/2026	01/10/2026	09/10/2026	15/10/2026
B35	26/08/2026	31/08/2026	05/10/2026	19/10/2026	22/10/2026	29/10/2026	06/11/2026	12/11/2026
B36	23/09/2026	28/09/2026	03/11/2026	16/11/2026	19/11/2026	26/11/2026	04/12/2026	10/12/2026

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(#) An updated AR is optional and dependent on the comments received from PRAC members and Marketing Authorisation Holders (MAHs) which create the need for the update.

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

90-day assessment timetable⁷

	Deadline for Submission (*)	Start date	Individual PRAC Rapporteurs/ Lead MSs AR (~)	Preliminary PRAC Rapporteur Joint AR	Comments from PRAC/MAH	Updated PRAC Rapporteur Joint AR (#)	PRAC conclusion	CAT opinion (^)	CHMP adoption (^)
C1	11/10/2023	14/10/2023	13/11/2023	12/12/2023	21/12/2023	04/01/2024	11/01/2024	19/01/2024	25/01/2024
C2	08/11/2023	11/11/2023	11/12/2023	09/01/2024	24/01/2024	01/02/2024	08/02/2024	16/02/2024	22/02/2024
C3	06/12/2023	09/12/2023	08/01/2024	06/02/2024	21/02/2024	29/02/2024	07/03/2024	15/03/2024	21/03/2024
C4	10/01/2024	13/01/2024	12/02/2024	12/03/2024	27/03/2024	04/04/2024	11/04/2024	19/04/2024	25/04/2024
C5	14/02/2024	17/02/2024	18/03/2024	16/04/2024	30/04/2024	08/05/2024	16/05/2024	24/05/2024	30/05/2024
C6	13/03/2024	16/03/2024	15/04/2024	14/05/2024	29/05/2024	06/06/2024	13/06/2024	21/06/2024	27/06/2024
C7	10/04/2024	13/04/2024	13/05/2024	11/06/2024	26/06/2024	04/07/2024	11/07/2024	19/07/2024	25/07/2024
C8									
C9	05/06/2024	08/06/2024	08/07/2024	06/08/2024	21/08/2024	29/08/2024	05/09/2024	13/09/2024	19/09/2024
C10	03/07/2024	06/07/2024	05/08/2024	03/09/2024	18/09/2024	26/09/2024	03/10/2024	11/10/2024	17/10/2024
C11	31/07/2024	03/08/2024	02/09/2024	01/10/2024	16/10/2024	24/10/2024	31/10/2024	08/11/2024	14/11/2024
C12	28/08/2024	31/08/2024	30/09/2024	29/10/2024	13/11/2024	21/11/2024	28/11/2024	06/12/2024	12/12/2024
C13	30/09/2024	03/10/2024	05/11/2024	04/12/2024	18/12/2024	09/01/2025	16/01/2025	24/01/2025	30/01/2025
C14	04/11/2024	08/11/2024	06/12/2024	13/01/2025	29/01/2025	06/02/2025	13/02/2025	21/02/2025	27/02/2025
C15	06/12/2024	09/12/2024	13/01/2025	11/02/2025	26/02/2025	06/03/2025	13/03/2025	21/03/2025	27/03/2025
C16	08/01/2025	11/01/2025	10/02/2025	11/03/2025	26/03/2025	03/04/2025	10/04/2025	16/04/2025	25/04/2025
C17	05/02/2025	08/02/2025	10/03/2025	08/04/2025	23/04/2025	02/05/2025	08/05/2025	16/05/2025	22/05/2025
C18	05/03/2025	08/03/2025	07/04/2025	06/05/2025	21/05/2025	28/05/2025	05/06/2025	13/06/2025	19/06/2025
C19	11/04/2025	14/04/2025	13/05/2025	10/06/2025	25/06/2025	03/07/2025	10/07/2025	18/07/2025	24/07/2025
C20									
C21	28/05/2025	30/05/2025	03/07/2025	05/08/2025	20/08/2025	28/08/2025	04/09/2025	12/10/2025	18/09/2025
C22	25/06/2025	27/06/2025	30/07/2025	02/09/2025	17/09/2025	25/09/2025	02/10/2025	10/10/2025	16/10/2025
C23	23/07/2025	25/07/2025	29/08/2025	30/09/2025	15/10/2025	23/10/2025	30/10/2025	07/11/2025	13/11/2025

	Deadline for Submission (*)	Start date	Individual PRAC Rapporteurs/ Lead MSs AR (~)	Preliminary PRAC Rapporteur Joint AR	Comments from PRAC/MAH	Updated PRAC Rapporteur Joint AR (#)	PRAC conclusion	CAT opinion (^)	CHMP adoption (^)
C24	27/08/2025	30/08/2025	29/09/2025	28/10/2025	12/11/2025	20/11/2025	27/11/2025	05/12/2025	11/12/2025
C25	08/10/2025	10/10/2025	10/11/2025	10/12/2025	05/01/2026	08/01/2026	15/01/2026	23/01/2026	29/01/2026
C26	05/11/2025	10/11/2025	08/12/2025	13/01/2026	28/01/2026	05/02/2026	12/02/2026	20/02/2026	26/02/2026
C27	05/12/2025	08/12/2025	12/01/2026	10/02/2026	25/02/2026	05/03/2026	12/03/2026	20/03/2026	26/03/2026
C28	07/01/2026	11/01/2026	09/02/2026	10/03/2026	25/03/2026	01/04/2026	10/04/2026	17/04/2026	23/04/2026
C29	04/02/2026	07/02/2026	09/03/2026	07/04/2026	22/04/2026	30/04/2026	07/05/2026	13/05/2026	21/05/2026
C30	11/03/2026	14/03/2026	13/04/2026	12/05/2026	27/05/2026	04/06/2026	11/06/2026	19/06/2026	25/06/2026
C31	13/04/2026	15/04/2026	13/05/2026	12/06/2026	26/06/2026	02/07/2026	09/07/2026	17/07/2026	23/07/2026
C32									
C33	27/05/2026	30/05/2026	30/06/2026	04/08/2026	19/08/2026	27/08/2026	03/09/2026	11/09/2026	17/09/2026
C34	24/06/2026	27/06/2026	29/07/2026	01/09/2026	16/09/2026	24/09/2026	01/10/2026	09/10/2026	15/10/2026
C35	22/07/2026	25/07/2026	28/08/2026	29/09/2026	14/10/2026	22/10/2026	29/10/2026	06/11/2026	12/11/2026
C36	26/08/2026	29/08/2026	28/09/2026	27/10/2026	11/11/2026	19/11/2026	26/11/2026	04/12/2026	10/12/2026

(-) The applicability of a 90-, 60- or 30-day timetable will be specified at the time of the preceding RSI.

(~) A Lead Member State (MS) is nominated in case of signals affecting only Nationally Authorised Products (NAPs) in order to carry out the preliminary assessment. This is in contrast to signals involving Centrally Authorised Products (CAPs) where the PRAC Rapporteurs of the CAPs circulate individual assessment reports which a nominated overall PRAC Rapporteur consolidates in a joint preliminary assessment report.

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(#) An updated AR is optional and dependent on the comments received from PRAC members and Marketing authorisation Holders (MAHs) which create the need for the update.

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