



25 February 2021
EMA/267915/2016 Rev.2
Human Medicines Division

An agency of the European Union



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 timetable[†]

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

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CAT adoption	CHMP adoption (^)
A43								
A44	28/07/2023	02/08/2023	16/08/2023	21/08/2023	24/08/2023	31/08/2023	08/09/2023	14/09/2023
A45	25/08/2023	30/08/2023	13/09/2023	18/09/2023	21/09/2023	28/09/2023	06/10/2023	12/10/2023
A46	22/09/2023	27/09/2023	11/10/2023	16/10/2023	19/10/2023	26/10/2023	31/10/2023	09/11/2023
A47	27/10/2023	01/11/2023	15/11/2023	20/11/2023	23/11/2023	30/11/2023	08/12/2023	14/12/2023
A48	24/11/2023	30/11/2023	14/12/2023	20/12/2023	05/01/2024	11/01/2024	19/01/2024	25/01/2024
A49	05/01/2024	10/01/2024	24/01/2024	29/01/2024	01/02/2024	08/02/2024	16/02/2024	22/02/2024
A50	02/02/2024	07/02/2024	21/02/2024	26/02/2024	29/02/2024	07/03/2024	15/03/2024	21/03/2024
A51	07/03/2024	12/03/2024	26/03/2024	02/04/2024	04/04/2024	11/04/2024	19/04/2024	25/04/2024
A52	12/04/2024	17/04/2024	02/05/2024	06/05/2024	08/05/2024	16/05/2024	24/05/2024	30/05/2024
A53	08/05/2024	15/05/2024	29/05/2024	03/06/2024	06/06/2024	13/06/2024	21/06/2024	27/06/2024
A54	07/06/2024	12/06/2024	26/06/2024	01/07/2024	04/07/2024	11/07/2024	19/07/2024	25/07/2024
A55								
A56	02/08/2024	07/08/2024	21/08/2024	26/08/2024	29/08/2024	05/09/2024	13/09/2024	19/09/2024
A57	30/08/2024	04/09/2024	18/09/2024	23/09/2024	26/09/2024	03/10/2024	11/10/2024	17/10/2024
A58	27/09/2024	02/10/2024	16/10/2024	21/10/2024	24/10/2024	31/10/2024	08/11/2024	14/11/2024
A59	25/10/2024	30/10/2024	13/11/2024	18/11/2024	21/11/2024	28/11/2024	06/12/2024	12/12/2024

(*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(#) 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.

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of centrally authorised products.

60-day assessment timetable⁷

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CAT adoption	CHMP adoption (^)
B1	08/01/2020	13/01/2020	17/02/2020	02/03/2020	05/03/2020	12/03/2020	20/03/2020	26/03/2020
B2	10/02/2020	18/02/2020	20/03/2020	03/04/2020	06/04/2020	17/04/2020	24/04/2020	30/04/2020
B3	11/03/2020	16/03/2020	20/04/2020	04/05/2020	07/05/2020	14/05/2020	20/05/2020	28/05/2020
B4	06/04/2020	13/04/2020	18/05/2020	28/05/2020	04/06/2020	11/06/2020	19/06/2020	25/06/2020
B5	06/05/2020	11/05/2020	15/06/2020	29/06/2020	02/07/2020	09/07/2020	17/07/2020	23/07/2020
B6								
B7	02/07/2020	07/07/2020	10/08/2020	24/08/2020	27/08/2020	04/09/2020	11/09/2020	17/09/2020
B8	29/07/2020	03/08/2020	07/09/2020	21/09/2020	24/09/2020	01/10/2020	09/10/2020	15/10/2020
B9	26/08/2020	31/08/2020	05/10/2020	19/10/2020	22/10/2020	29/10/2020	06/11/2020	12/11/2020
B10	23/09/2020	28/09/2020	04/11/2020	16/11/2020	19/11/2020	26/11/2020	04/12/2020	10/12/2020
B11	11/11/2020	16/11/2020	21/12/2020	04/01/2021	07/01/2021	14/01/2021	22/01/2021	28/01/2021
B12	09/12/2020	14/12/2020	18/01/2021	01/02/2021	04/02/2021	11/02/2021	19/02/2021	25/02/2021
B13	06/01/2021	11/01/2021	15/02/2021	01/03/2021	04/03/2021	11/03/2021	19/03/2021	25/03/2021
B14	04/02/2021	09/02/2021	15/03/2021	29/03/2021	31/03/2021	09/04/2021	16/04/2021	22/04/2021
B15	03/03/2021	08/03/2021	12/04/2021	26/04/2021	29/04/2021	06/05/2021	12/05/2021	20/05/2021
B16	07/04/2021	12/04/2021	17/05/2021	31/05/2021	03/06/2021	10/06/2021	18/06/2021	24/06/2021
B17	05/05/2021	10/05/2021	14/06/2021	28/06/2021	01/07/2021	08/07/2021	16/07/2021	22/07/2021
B18								
B19	01/07/2021	06/07/2021	09/08/2021	23/08/2021	26/08/2021	03/09/2021	10/09/2021	16/09/2021
B20	28/07/2021	02/08/2021	06/09/2021	20/09/2021	23/09/2021	30/09/2021	08/10/2021	14/10/2021
B21	25/08/2021	30/08/2021	04/10/2021	18/10/2021	21/10/2021	28/10/2021	05/11/2021	11/11/2021
B22	29/09/2021	04/10/2021	08/11/2021	22/11/2021	25/11/2021	02/12/2021	10/12/2021	16/12/2021
B23	03/11/2021	09/11/2021	08/12/2021	20/12/2021	06/01/2022	13/01/2022	21/01/2022	27/01/2022
B24	08/12/2021	13/12/2021	17/01/2022	31/01/2022	03/02/2022	10/02/2022	18/02/2022	24/02/2022
B25	05/01/2022	10/01/2022	14/02/2022	28/02/2022	03/03/2022	10/03/2022	18/03/2022	24/03/2022
B26	02/02/2022	07/02/2022	14/03/2022	28/03/2022	31/03/2022	07/04/2022	13/04/2022	22/04/2022
B27	02/03/2022	07/03/2022	11/04/2022	25/04/2022	28/04/2022	05/05/2022	13/05/2022	19/05/2022
B28	07/04/2022	12/04/2022	16/05/2022	30/05/2022	03/06/2022	10/06/2022	17/06/2022	23/06/2022
B29	04/05/2022	09/05/2022	13/06/2022	27/06/2022	30/06/2022	07/07/2022	15/07/2022	21/07/2022
B30								
B31	29/06/2022	04/07/2022	08/08/2022	22/08/2022	25/08/2022	01/09/2022	09/09/2022	15/09/2022
B32	27/07/2022	01/08/2022	05/09/2022	19/09/2022	22/09/2022	29/09/2022	07/10/2022	13/10/2022
B33	24/08/2022	29/08/2022	03/10/2022	17/10/2022	20/10/2022	27/10/2022	04/11/2022	10/11/2022
B34	28/09/2022	03/10/2022	07/11/2022	21/11/2022	24/11/2022	01/12/2022	09/12/2022	15/12/2022
B35	03/11/2022	09/11/2022	08/12/2022	20/12/2022	05/01/2023	12/01/2023	20/01/2023	26/01/2023
B36	07/12/2022	12/12/2022	16/01/2023	30/01/2023	02/02/2023	09/02/2023	17/02/2023	23/02/2023
B37	11/01/2023	16/01/2023	20/02/2023	06/03/2023	09/03/2023	16/03/2023	24/03/2023	30/03/2023
B38	09/02/2023	14/02/2023	20/03/2023	03/04/2023	05/04/2023	14/04/2023	21/04/2023	26/04/2023
B39	09/03/2023	14/03/2023	17/04/2023	02/05/2023	04/05/2023	12/05/2023	17/05/2023	25/05/2023
B40	05/04/2023	10/04/2023	15/05/2023	26/05/2023	01/06/2023	08/06/2023	16/06/2023	22/06/2023
B41	03/05/2023	08/05/2023	12/06/2023	26/06/2023	29/06/2023	06/07/2023	14/07/2023	20/07/2023
B42								

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CAT adoption	CHMP adoption (^)
B43	28/06/2023	03/07/2023	07/08/2023	21/08/2023	24/08/2023	31/08/2023	08/09/2023	14/09/2023
B44	26/07/2023	31/07/2023	04/09/2023	18/09/2023	21/09/2023	28/09/2023	06/10/2023	12/10/2023
B45	23/08/2023	28/08/2023	02/10/2023	16/10/2023	19/10/2023	26/10/2023	31/10/2023	09/11/2023
B46	27/09/2023	02/10/2023	06/11/2023	20/11/2023	23/11/2023	30/11/2023	08/12/2023	14/12/2023
B47	30/10/2023	07/11/2023	06/12/2023	19/12/2023	05/01/2024	11/01/2024	19/01/2024	25/01/2024
B48	06/12/2023	11/12/2023	15/01/2024	29/01/2024	01/02/2024	08/02/2024	16/02/2024	22/02/2024
B49	03/01/2024	08/01/2024	12/02/2024	26/02/2024	29/02/2024	07/03/2024	15/03/2024	21/03/2024
B50	07/02/2024	12/02/2024	18/03/2024	02/04/2024	04/04/2024	11/04/2024	19/04/2024	25/04/2024
B51	13/03/2024	18/03/2024	22/04/2024	06/05/2024	08/05/2024	16/05/2024	24/05/2024	30/05/2024
B52	10/04/2024	15/04/2024	21/05/2024	03/06/2024	06/06/2024	13/06/2024	21/06/2024	27/06/2024
B53	08/05/2024	13/05/2024	17/06/2024	01/07/2024	04/07/2024	11/07/2024	19/07/2024	25/07/2024
B54								
B55	03/07/2024	08/07/2024	12/08/2024	26/08/2024	29/08/2024	05/09/2024	13/09/2024	19/09/2024
B56	31/07/2024	05/08/2024	09/09/2024	23/09/2024	26/09/2024	03/10/2024	11/10/2024	17/10/2024
B57	28/08/2024	02/09/2024	07/10/2024	21/10/2024	24/10/2024	31/10/2024	08/11/2024	14/11/2024
B58	25/09/2024	30/09/2024	04/11/2024	18/11/2024	21/11/2024	28/11/2024	06/12/2024	12/12/2024

(*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(#) 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.

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of centrally authorised products.

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 adoption	CHMP adoption (^)
C1	10/01/2020	19/01/2020	14/02/2020	13/03/2020	27/03/2020	06/04/2020	17/04/2020	24/04/2020	30/04/2020
C2	12/02/2020	15/02/2020	16/03/2020	14/04/2020	29/04/2020	07/05/2020	14/05/2020	20/05/2020	28/05/2020
C3	06/03/2020	14/03/2020	15/04/2020	13/05/2020	27/05/2020	04/06/2020	11/06/2020	19/06/2020	25/06/2020
C4	08/04/2020	11/04/2020	11/05/2020	09/06/2020	24/06/2020	02/07/2020	09/07/2020	17/07/2020	23/07/2020
C5									
C6	04/06/2020	07/06/2020	06/07/2020	04/08/2020	19/08/2020	27/08/2020	04/09/2020	11/09/2020	17/09/2020
C7	01/07/2020	04/07/2020	03/08/2020	01/09/2020	16/09/2020	24/09/2020	01/10/2020	09/10/2020	15/10/2020
C8	29/07/2020	01/08/2020	01/09/2020	29/09/2020	14/10/2020	22/10/2020	29/10/2020	06/11/2020	12/11/2020
C9	26/08/2020	29/08/2020	28/09/2020	27/10/2020	11/11/2020	19/11/2020	26/11/2020	04/12/2020	10/12/2020
C10	14/10/2020	17/10/2020	16/11/2020	15/12/2020	04/01/2021	07/01/2021	14/01/2021	22/01/2021	28/01/2021
C11	11/11/2020	14/11/2020	14/12/2020	12/01/2021	27/01/2021	04/02/2021	11/02/2021	19/02/2021	25/02/2021
C12	09/12/2020	12/12/2020	11/01/2021	09/02/2021	24/02/2021	04/03/2021	11/03/2021	19/03/2021	25/03/2021
C13	07/01/2021	10/01/2021	08/02/2021	09/03/2021	24/03/2021	31/03/2021	09/04/2021	16/04/2021	22/04/2021
C14	03/02/2021	06/02/2021	08/03/2021	06/04/2021	21/04/2021	29/04/2021	06/05/2021	12/05/2021	20/05/2021
C15	10/03/2021	13/03/2021	12/04/2021	11/05/2021	26/05/2021	03/06/2021	10/06/2021	18/06/2021	24/06/2021
C16	07/04/2021	10/04/2021	10/05/2021	08/06/2021	23/06/2021	01/07/2021	08/07/2021	16/07/2021	22/07/2021
C17									
C18	03/06/2021	06/06/2021	05/07/2021	03/08/2021	18/08/2021	26/08/2021	03/09/2021	10/09/2021	16/09/2021
C19	30/06/2021	03/07/2021	02/08/2021	31/08/2021	15/09/2021	23/09/2021	30/09/2021	08/10/2021	14/10/2021
C20	28/07/2021	31/07/2021	31/08/2021	28/09/2021	13/10/2021	21/10/2021	28/10/2021	05/11/2021	11/11/2021
C21	01/09/2021	04/09/2021	04/10/2021	03/11/2021	17/11/2021	25/11/2021	02/12/2021	10/12/2021	16/12/2021
C22	13/10/2021	16/10/2021	15/11/2021	14/12/2021	03/01/2022	06/01/2022	13/01/2022	21/01/2022	27/01/2022
C23	10/11/2021	13/11/2021	13/12/2021	11/01/2022	26/01/2022	03/02/2022	10/02/2022	18/02/2022	24/02/2022
C24	08/12/2021	11/12/2021	10/01/2022	08/02/2022	23/02/2022	03/03/2022	10/03/2022	18/03/2022	24/03/2022
C25	05/01/2022	08/01/2022	07/02/2022	08/03/2022	23/03/2022	31/03/2022	07/04/2022	13/04/2022	22/04/2022
C26	02/02/2022	05/02/2022	07/03/2022	05/04/2022	20/04/2022	28/04/2022	05/05/2022	13/05/2022	19/05/2022
C27	10/03/2022	13/03/2022	11/04/2022	10/05/2022	25/05/2022	02/06/2022	10/06/2022	17/06/2022	23/06/2022
C28	06/04/2022	09/04/2022	10/05/2022	07/06/2022	22/06/2022	30/06/2022	07/07/2022	15/07/2022	21/07/2022
C29									
C30	01/06/2022	04/06/2022	04/07/2022	02/08/2022	17/08/2022	25/08/2022	01/09/2022	09/09/2022	15/09/2022
C31	29/06/2022	02/07/2022	01/08/2022	30/08/2022	14/09/2022	22/09/2022	29/09/2022	07/10/2022	13/10/2022
C32	27/07/2022	30/07/2022	29/08/2022	27/09/2022	12/10/2022	20/10/2022	27/10/2022	04/11/2022	10/11/2022
C33	31/08/2022	03/09/2022	03/10/2022	03/11/2022	16/11/2022	24/11/2022	01/12/2022	09/12/2022	15/12/2022
C34	06/10/2022	12/10/2022	10/11/2022	09/12/2022	20/12/2022	05/01/2023	12/01/2023	20/01/2023	26/01/2023
C35	09/11/2022	12/11/2022	12/12/2022	10/01/2023	25/01/2023	02/02/2023	09/02/2023	17/02/2023	23/02/2023
C36	14/12/2022	17/12/2022	16/01/2023	14/02/2023	01/03/2023	09/03/2023	16/03/2023	24/03/2023	30/03/2023
C37	12/01/2023	15/01/2023	13/02/2023	14/03/2023	29/03/2023	05/04/2023	14/04/2023	21/04/2023	26/04/2023
C38	09/02/2023	12/02/2023	13/03/2023	11/04/2023	26/04/2023	04/05/2023	12/05/2023	17/05/2023	25/05/2023
C39	08/03/2023	11/03/2023	11/04/2023	10/05/2023	24/05/2023	01/06/2023	08/06/2023	16/06/2023	22/06/2023

	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 adoption	CHMP adoption (^)
C40	05/04/2023	08/04/2023	08/05/2023	06/06/2023	21/06/2023	29/06/2023	06/07/2023	14/07/2023	20/07/2023
C41									
C42	31/05/2023	03/06/2023	03/07/2023	01/08/2023	16/08/2023	24/08/2023	31/08/2023	08/09/2023	14/09/2023
C43	28/06/2023	01/07/2023	31/07/2023	29/08/2023	13/09/2023	21/09/2023	28/09/2023	06/10/2023	12/10/2023
C44	26/07/2023	29/07/2023	28/08/2023	26/09/2023	11/10/2023	19/10/2023	26/10/2023	31/10/2023	09/11/2023
C45	30/08/2023	02/09/2023	02/10/2023	31/10/2023	15/11/2023	23/11/2023	30/11/2023	08/12/2023	14/12/2023
C46	05/10/2023	11/10/2023	10/11/2023	08/12/2023	19/12/2023	04/01/2024	11/01/2024	19/01/2024	25/01/2024
C47	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
C48	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
C49	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
C50	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
C51	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
C52	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
C53									
C54	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
C55	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
C56	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
C57	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

(-) 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.

(*) 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.

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of centrally authorised products.