



25 February 2021
EMA/403963/2015 Rev.4
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)

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

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CHMP adoption (^)
A40	05/04/2023	13/04/2023	26/04/2023	02/05/2023	04/05/2023	12/05/2023	25/05/2023
A41	05/05/2023	10/05/2023	24/05/2023	30/05/2023	01/06/2023	08/06/2023	22/06/2023
A42	02/06/2023	07/06/2023	21/06/2023	26/06/2023	29/06/2023	06/07/2023	20/07/2023

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

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

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

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

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

(*) 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	CHMP adoption (^)
C1	10/01/2020	19/01/2020	14/02/2020	13/03/2020	27/03/2020	06/04/2020	17/04/2020	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	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	22/06/2023
C40	05/04/2023	08/04/2023	08/05/2023	06/06/2023	21/06/2023	29/06/2023	06/07/2023	20/07/2023

	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	CHMP adoption (^)
C41								
C42	31/05/2023	03/06/2023	03/07/2023	01/08/2023	16/08/2023	24/08/2023	31/08/2023	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	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	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	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	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	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	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	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	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	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	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	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	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	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	12/12/2024

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

(~) This step may apply in case the signal involves several active substances/products (e.g. class issues).

In such cases, individual assessments may be carried out by the relevant Lead Member State(s) according to the [List of substances and products subject to worksharing for signal management](#) (for nationally authorised products - NAPs) and/or the relevant PRAC Rapporteurs (for centrally authorised products - CAPs), before a joint assessment report is prepared by the PRAC-appointed Rapporteur for the evaluation of the signal.

(*) 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 CAPs.