



9 December 2021
EMA/727192/2017 Rev.2
Human Medicines Division

The timetables in this document may be subject to revision

Type II variation and worksharing application assessment timetables - ATMP

Initial submission assessment timetable

[90-day](#)

[60-day](#)

[30-day](#)

Responses to Request for Supplementary Information (RSI) assessment timetable

[60-day after clockstop](#)

[30-day after clockstop](#)

[30-day after immediate responses](#)

90-day initial submission assessment timetable⁷

	Deadline for Submission (*)	Start date (^)	CAT (Co-) Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
A1	15/01/2020	01/02/2020	27/03/2020	02/04/2020	06/04/2020	07/04/2020	14/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
A2	10/02/2020	27/02/2020	22/04/2020	29/04/2020	04/05/2020	07/05/2020	11/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
A3	11/03/2020	28/03/2020	20/05/2020	29/05/2020	03/06/2020	04/06/2020	09/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
A4	08/04/2020	25/04/2020	19/06/2020	26/06/2020	01/07/2020	02/07/2020	07/07/2020	09/07/2020	13/07/2020	17/07/2020	23/07/2020
A5											
A6	03/06/2020	20/06/2020	14/08/2020	21/08/2020	26/08/2020	27/08/2020	01/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
A7	01/07/2020	18/07/2020	11/09/2020	18/09/2020	23/09/2020	24/09/2020	29/09/2020	01/10/2020	05/10/2020	09/10/2020	15/10/2020
A8	29/07/2020	15/08/2020	09/10/2020	16/10/2020	21/10/2020	22/10/2020	27/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020
A9	26/08/2020	12/09/2020	06/11/2020	13/11/2020	18/11/2020	19/11/2020	24/11/2020	26/11/2020	30/11/2020	04/12/2020	10/12/2020
A10	14/10/2020	31/10/2020	22/12/2020	04/01/2021	06/01/2021	07/01/2021	12/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
A11	11/11/2020	28/11/2020	22/01/2021	29/01/2021	03/02/2021	04/02/2021	09/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
A12	25/11/2020	26/12/2020	19/02/2021	26/02/2021	03/03/2021	04/03/2021	09/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
A13	06/01/2021	23/01/2021	19/03/2021	25/03/2021	29/03/2021	30/03/2021	06/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
A14	01/02/2021	18/02/2021	14/04/2021	21/04/2021	26/04/2021	29/04/2021	03/05/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
A15	10/03/2021	27/03/2021	21/05/2021	28/05/2021	02/06/2021	03/06/2021	08/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
A16	07/04/2021	24/04/2021	18/06/2021	25/06/2021	30/06/2021	01/07/2021	06/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
A17											
A18	02/06/2021	19/06/2021	13/08/2021	20/08/2021	25/08/2021	26/08/2021	31/08/2021	02/09/2021	06/09/2021	10/09/2021	16/09/2021
A19	30/06/2021	17/07/2021	10/09/2021	17/09/2021	22/09/2021	23/09/2021	28/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
A20	28/07/2021	14/08/2021	08/10/2021	15/10/2021	20/10/2021	21/10/2021	26/10/2021	28/10/2021	29/10/2021	05/11/2021	11/11/2021
A21	01/09/2021	18/09/2021	12/11/2021	19/11/2021	24/11/2021	25/11/2021	30/11/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
A22	13/10/2021	30/10/2021	22/12/2021	03/01/2022	05/01/2022	06/01/2022	11/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
A23	10/11/2021	27/11/2021	21/01/2022	28/01/2022	02/02/2022	03/02/2022	08/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022
A24	01/12/2021	25/12/2021	18/02/2022	25/02/2022	02/03/2022	03/03/2022	08/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022

	Deadline for Submission (*)	Start date (^)	CAT (Co-) Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
A25	03/01/2022	20/01/2022	18/03/2022	25/03/2022	30/03/2022	31/03/2022	05/04/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
A26	02/02/2022	19/02/2022	13/04/2022	22/04/2022	26/04/2022	28/04/2022	03/05/2022	05/05/2022	06/05/2022	13/05/2022	19/05/2022
A27	09/03/2022	26/03/2022	20/05/2022	25/05/2022	01/06/2022	02/06/2022	07/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
A28	06/04/2022	23/04/2022	17/06/2022	24/06/2022	29/06/2022	30/06/2022	05/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
A29											
A30	01/06/2022	18/06/2022	12/08/2022	19/08/2022	24/08/2022	25/08/2022	30/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
A31	29/06/2022	16/07/2022	09/09/2022	16/09/2022	21/09/2022	22/09/2022	27/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
A32	27/07/2022	13/08/2022	07/10/2022	14/10/2022	19/10/2022	20/10/2022	25/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
A33	31/08/2022	17/09/2022	11/11/2022	18/11/2022	23/11/2022	24/11/2022	29/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
A34	12/10/2022	29/10/2022	22/12/2022	03/01/2023	04/01/2023	05/01/2023	10/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
A35	09/11/2022	26/11/2022	20/01/2023	27/01/2023	01/02/2023	02/02/2023	07/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
A36	30/11/2022	31/12/2022	24/02/2023	03/03/2023	08/03/2023	09/03/2023	14/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
A37	11/01/2023	28/01/2023	24/03/2023	31/03/2023	04/04/2023	05/04/2023	11/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
A38	06/02/2023	23/02/2023	21/04/2023	28/04/2023	03/05/2023	04/05/2023	08/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
A39	08/03/2023	25/03/2023	17/05/2023	26/05/2023	31/05/2023	01/06/2023	06/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
A40	05/04/2023	22/04/2023	16/06/2023	23/06/2023	28/06/2023	29/06/2023	04/07/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
A41											
A42	31/05/2023	17/06/2023	11/08/2023	18/08/2023	23/08/2023	24/08/2023	29/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
A43	28/06/2023	15/07/2023	08/09/2023	15/09/2023	20/09/2023	21/09/2023	26/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
A44	24/07/2023	09/08/2023	06/10/2023	13/10/2023	18/10/2023	19/10/2023	24/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
A45	30/08/2023	16/09/2023	10/11/2023	17/11/2023	22/11/2023	23/11/2023	28/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
A46	11/10/2023	28/10/2023	21/12/2023	03/01/2024	04/01/2024	05/01/2024	09/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
A47	08/11/2023	25/11/2023	19/01/2024	26/01/2024	31/01/2024	01/02/2024	06/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
A48	29/11/2023	23/12/2023	16/02/2024	23/02/2024	28/02/2024	29/02/2024	05/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
A49	10/01/2024	27/01/2024	22/03/2024	27/03/2024	03/04/2024	04/04/2024	09/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024
A50	14/02/2024	02/03/2024	26/04/2024	03/05/2024	07/05/2024	08/05/2024	14/05/2024	16/05/2024	21/05/2024	24/05/2024	30/05/2024

	Deadline for Submission (*)	Start date (^)	CAT (Co-) Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
A51	13/03/2024	30/03/2024	24/05/2024	31/05/2024	05/06/2024	06/06/2024	11/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
A52	10/04/2024	27/04/2024	21/06/2024	28/06/2024	03/07/2024	04/07/2024	09/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
A53											
A54	05/06/2024	22/06/2024	16/08/2024	23/08/2024	28/08/2024	29/08/2024	03/09/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
A55	03/07/2024	20/07/2024	13/09/2024	20/09/2024	25/09/2024	26/09/2024	01/10/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
A56	31/07/2024	17/08/2024	11/10/2024	18/10/2024	23/10/2024	24/10/2024	29/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
A57	28/08/2024	14/09/2024	08/11/2024	15/11/2024	20/11/2024	21/11/2024	26/11/2024	28/11/2024	02/12/2024	06/12/2024	12/12/2024

(-) This timetable is only applicable to variations concerning a change to or addition of therapeutic indications and potentially to groupings of variations (in case of grouped variations, a 90-day assessment timetable should be agreed with the Agency at the time of validation of the application).

(^) The validation period between submission date and start date is usually sixteen calendar days.

(*) 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.

(~) Step applicable only if the submission falls (at least partially) under the remit of the PRAC (typically, when a RMP is submitted).

(**) Comments from CAT, CHMP and PRAC members are not made available to Applicants.

(***) An updated AR is optional and dependent on the comments received from committee (PRAC, CAT, CHMP) members which create the need for the update.

(#) Step applicable only in case of CAT Opinion (not applicable in case a Request for Supplementary Information is adopted by the CAT).

60-day initial submission assessment timetable⁷

	Deadline for Submission (*)	Start date (^)	CAT Rapporteur AR (!)	CAT Rapporteur AR (~)	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
B1	10/01/2020	27/01/2020	02/03/2020	25/02/2020	28/02/2020	04/03/2020	05/03/2020	11/03/2020	12/03/2020	16/03/2020	20/03/2020	26/03/2020
B2	14/02/2020	02/03/2020	06/04/2020	31/03/2020	03/04/2020	07/04/2020	08/04/2020	15/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
B3	11/03/2020	28/03/2020	04/05/2020	27/04/2020	29/04/2020	06/05/2020	07/05/2020	13/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
B4	08/04/2020	27/04/2020	02/06/2020	26/05/2020	29/05/2020	03/06/2020	04/06/2020	10/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
B5	08/05/2020	25/05/2020	29/06/2020	23/06/2020	26/06/2020	01/07/2020	02/07/2020	08/07/2020	09/07/2020	13/07/2020	17/07/2020	23/07/2020
B6												
B7	03/07/2020	20/07/2020	24/08/2020	18/08/2020	21/08/2020	26/08/2020	27/08/2020	02/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
B8	31/07/2020	17/08/2020	21/09/2020	15/09/2020	18/09/2020	23/09/2020	24/09/2020	30/09/2020	01/10/2020	05/10/2020	09/10/2020	15/10/2020
B9	28/08/2020	14/09/2020	19/10/2020	13/10/2020	16/10/2020	21/10/2020	22/10/2020	28/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020
B10	25/09/2020	12/10/2020	16/11/2020	10/11/2020	13/11/2020	18/11/2020	19/11/2020	25/11/2020	26/11/2020	30/11/2020	04/12/2020	10/12/2020
B11	13/11/2020	30/11/2020	04/01/2021	22/12/2020	04/01/2021	06/01/2021	07/01/2021	13/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
B12	27/11/2020	28/12/2020	01/02/2021	26/01/2021	29/01/2021	03/02/2021	04/02/2021	10/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
B13	08/01/2021	25/01/2021	01/03/2021	23/02/2021	26/02/2021	03/03/2021	04/03/2021	10/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
B14	05/02/2021	22/02/2021	29/03/2021	23/03/2021	26/03/2021	30/03/2021	31/03/2021	07/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
B15	03/03/2021	20/03/2021	26/04/2021	19/04/2021	21/04/2021	28/04/2021	29/04/2021	05/05/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
B16	09/04/2021	26/04/2021	31/05/2021	25/05/2021	28/05/2021	02/06/2021	03/06/2021	09/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
B17	07/05/2021	24/05/2021	28/06/2021	22/06/2021	25/06/2021	30/06/2021	01/07/2021	07/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
B18												
B19	02/07/2021	19/07/2021	23/08/2021	17/08/2021	20/08/2021	25/08/2021	26/08/2021	01/09/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
B20	30/07/2021	16/08/2021	20/09/2021	14/09/2021	17/09/2021	22/09/2021	23/09/2021	29/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
B21	27/08/2021	13/09/2021	18/10/2021	12/10/2021	15/10/2021	20/10/2021	21/10/2021	27/10/2021	28/10/2021	29/10/2021	05/11/2021	11/11/2021
B22	01/10/2021	18/10/2021	22/11/2021	16/11/2021	19/11/2021	24/11/2021	25/11/2021	01/12/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
B23	12/11/2021	29/11/2021	03/01/2022	22/12/2021	03/01/2022	05/01/2022	06/01/2022	12/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
B24	26/11/2021	27/12/2021	31/01/2022	25/01/2022	28/01/2022	02/02/2022	03/02/2022	09/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022

	Deadline for Submission (*)	Start date (^)	CAT Rapporteur AR (!)	CAT Rapporteur AR (~)	PRAC Rapporteur AR (~)	Comments from PRAC (**)(~)	Updated PRAC Rapporteur AR (***)(~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
B25	07/01/2022	24/01/2022	28/02/2022	22/02/2022	25/02/2022	02/03/2022	03/03/2022	09/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
B26	02/02/2022	19/02/2022	28/03/2022	22/03/2022	25/03/2022	30/03/2022	31/03/2022	06/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
B27	04/03/2022	21/03/2022	25/04/2022	19/04/2022	22/04/2022	26/04/2022	28/04/2022	04/05/2022	05/05/2022	10/05/2022	13/05/2022	19/05/2022
B28	08/04/2022	25/04/2022	30/05/2022	24/05/2022	30/05/2022	01/06/2022	02/06/2022	08/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
B29	06/05/2022	23/05/2022	27/06/2022	21/06/2022	24/06/2022	29/06/2022	30/06/2022	06/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
B30												
B31	01/07/2022	18/07/2022	22/08/2022	16/08/2022	19/08/2022	24/08/2022	25/08/2022	31/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
B32	29/07/2022	15/08/2022	19/09/2022	13/09/2022	16/09/2022	21/09/2022	22/09/2022	28/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
B33	26/08/2022	12/09/2022	17/10/2022	11/10/2022	14/10/2022	19/10/2022	20/10/2022	26/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
B34	30/09/2022	17/10/2022	21/11/2022	15/11/2022	18/11/2022	23/11/2022	24/11/2022	30/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
B35	11/11/2022	28/11/2022	03/01/2023	22/12/2022	03/01/2023	05/01/2023	06/01/2023	11/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
B36	25/11/2022	26/12/2022	30/01/2023	24/01/2023	27/01/2023	01/02/2023	02/02/2023	08/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
B37	13/01/2023	30/01/2023	06/03/2023	28/02/2023	03/03/2023	08/03/2023	09/03/2023	15/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
B38	10/02/2023	27/02/2023	03/04/2023	28/03/2023	31/03/2023	04/04/2023	05/04/2023	12/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
B39	08/03/2023	25/03/2023	02/05/2023	25/04/2023	28/04/2023	03/05/2023	04/05/2023	10/05/2023	12/05/2023	12/05/2023	17/05/2023	25/05/2023
B40	07/04/2023	24/04/2023	30/05/2023	23/05/2023	26/05/2023	31/05/2023	01/06/2023	07/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
B41	05/05/2023	22/05/2023	26/06/2023	20/06/2023	23/06/2023	28/06/2023	29/06/2023	05/07/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
B42												
B43	30/06/2023	17/07/2023	21/08/2023	14/08/2023	18/08/2023	23/08/2023	24/08/2023	30/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
B44	28/07/2023	14/08/2023	18/09/2023	12/09/2023	15/09/2023	20/09/2023	21/09/2023	27/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
B45	22/08/2023	08/09/2023	16/10/2023	10/10/2023	13/10/2023	18/10/2023	19/10/2023	25/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
B46	29/09/2023	16/10/2023	20/11/2023	14/11/2023	17/11/2023	22/11/2023	23/11/2023	29/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
B47	10/11/2023	27/11/2023	03/01/2024	21/12/2023	03/01/2024	04/01/2024	05/01/2024	10/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
B48	24/11/2023	25/12/2023	29/01/2024	23/01/2024	26/01/2024	31/01/2024	01/02/2024	07/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
B49	05/01/2024	22/01/2024	26/02/2024	20/02/2024	23/02/2024	28/02/2024	29/02/2024	06/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
B50	09/02/2024	26/02/2024	02/04/2024	25/03/2024	27/03/2024	03/04/2024	04/04/2024	10/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024

	Deadline for Submission (*)	Start date (^)	CAT Rapporteur AR (!)	CAT Rapporteur AR (~)	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
B51	15/03/2024	01/04/2024	06/05/2024	30/04/2024	03/05/2024	07/05/2024	08/05/2024	15/05/2024	16/05/2024	17/05/2024	24/05/2024	30/05/2024
B52	12/04/2024	29/04/2024	03/06/2024	28/05/2024	31/05/2024	05/06/2024	06/06/2024	12/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
B53	10/05/2024	27/05/2024	01/07/2024	25/06/2024	28/06/2024	03/07/2024	04/07/2024	10/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
B54												
B55	05/07/2024	22/07/2024	26/08/2024	20/08/2024	23/08/2024	28/08/2024	29/08/2024	04/09/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
B56	02/08/2024	19/08/2024	23/09/2024	17/09/2024	20/09/2024	25/09/2024	26/09/2024	02/10/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
B57	30/08/2024	16/09/2024	21/10/2024	15/10/2024	18/10/2024	23/10/2024	24/10/2024	30/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
B58	27/09/2024	14/10/2024	18/11/2024	12/11/2024	15/11/2024	20/11/2024	21/11/2024	27/11/2024	28/11/2024	02/12/2024	06/12/2024	12/12/2024

(-) This is the default timetable for type II variations, unless there are reasons to extend the assessment time to 90 days or reduce it to 30 days.

(*) 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.

(^) The validation period between submission date and start date is usually sixteen calendar days.

(!) Step applicable if the PRAC is not involved (i.e. no RMP or or results of non-interventional Post-Authorisation Safety Study (PASS) are submitted).

(~) Step applicable only if the submission falls (at least partially) under the remit of the PRAC (typically, when a RMP is submitted). For PRAC-led variations (including only an RMP or final results of non-interventional PASS with no consequences to Product Information), only the PRAC Rapporteur produces an AR.

(**) Comments from CAT, CHMP and PRAC members are not made available to Applicants.

(***) An updated AR is optional and dependent on the comments received from committee (PRAC, CAT, CHMP) members which create the need for the update.

(#) Step applicable only in case of CAT Opinion (not applicable in case a Request for Supplementary Information is adopted by the CAT).

30-day initial submission assessment timetable⁷

	Deadline for Submission (*)	Start date (^)	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**)(~)	Updated PRAC Rapporteur AR (***)(~)	PRAC outcome (~)	Comments from CAT and CHMP (**)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
C1	17/01/2020	29/01/2020	11/02/2020	03/02/2020	05/02/2020	06/02/2020	13/02/2020	14/02/2020	17/02/2020	21/02/2020	27/02/2020
C2	14/02/2020	26/02/2020	10/03/2020	02/03/2020	04/03/2020	05/03/2020	12/03/2020	13/03/2020	16/03/2020	20/03/2020	26/03/2020
C3	20/03/2020	01/04/2020	14/04/2020	06/04/2020	07/04/2020	08/04/2020	17/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
C4	15/04/2020	27/04/2020	12/05/2020	04/05/2020	06/05/2020	07/05/2020	14/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
C5	15/05/2020	27/05/2020	09/06/2020	02/06/2020	03/06/2020	04/06/2020	11/06/2020	12/06/2020	15/06/2020	19/06/2020	25/06/2020
C6	12/06/2020	24/06/2020	07/07/2020	29/06/2020	01/07/2020	02/07/2020	09/07/2020	10/07/2020	13/07/2020	17/07/2020	23/07/2020
C7											
C8	07/08/2020	19/08/2020	01/09/2020	24/08/2020	26/08/2020	27/08/2020	04/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
C9	04/09/2020	16/09/2020	29/09/2020	21/09/2020	23/09/2020	24/09/2020	01/10/2020	02/10/2020	05/10/2020	09/10/2020	15/10/2020
C10	02/10/2020	14/10/2020	27/10/2020	19/10/2020	21/10/2020	22/10/2020	29/10/2020	30/10/2020	03/11/2020	06/11/2020	12/11/2020
C11	30/10/2020	11/11/2020	24/11/2020	16/11/2020	18/11/2020	19/11/2020	26/11/2020	27/11/2020	30/11/2020	04/12/2020	10/12/2020
C12	27/11/2020	30/12/2020	12/01/2021	04/01/2021	06/01/2021	07/01/2021	14/01/2021	15/01/2021	18/01/2021	22/01/2021	28/01/2021
C13	15/01/2021	27/01/2021	09/02/2021	01/02/2021	03/02/2021	04/02/2021	11/02/2021	12/02/2021	15/02/2021	19/02/2021	25/02/2021
C14	12/02/2021	24/02/2021	09/03/2021	01/03/2021	03/03/2021	04/03/2021	11/03/2021	12/03/2021	15/03/2021	19/03/2021	25/03/2021
C15	12/03/2021	24/03/2021	06/04/2021	26/03/2021	29/03/2021	30/03/2021	09/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
C16	07/04/2021	19/04/2021	04/05/2021	26/04/2021	28/04/2021	29/04/2021	06/05/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
C17	12/05/2021	26/05/2021	08/06/2021	31/05/2021	02/06/2021	03/06/2021	10/06/2021	11/06/2021	14/06/2021	18/06/2021	24/06/2021
C18	11/06/2021	23/06/2021	06/07/2021	28/06/2021	30/06/2021	01/07/2021	08/07/2021	09/07/2021	12/07/2021	16/07/2021	22/07/2021
C19											
C20	06/08/2021	18/08/2021	31/08/2021	23/08/2021	25/08/2021	26/08/2021	03/09/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
C21	03/09/2021	15/09/2021	28/09/2021	20/09/2021	22/09/2021	23/09/2021	30/09/2021	01/10/2021	04/10/2021	08/10/2021	14/10/2021
C22	01/10/2021	13/10/2021	26/10/2021	18/10/2021	20/10/2021	21/10/2021	28/10/2021	29/10/2021	29/10/2021	05/11/2021	11/11/2021
C23	05/11/2021	17/11/2021	30/11/2021	22/11/2021	24/11/2021	25/11/2021	02/12/2021	03/12/2021	06/12/2021	10/12/2021	16/12/2021
C24	01/12/2021	29/12/2021	11/01/2022	03/01/2022	05/01/2022	06/01/2022	13/01/2022	14/01/2022	17/01/2022	21/01/2022	27/01/2022
C25	14/01/2022	26/01/2022	08/02/2022	31/01/2022	02/02/2022	03/02/2022	10/02/2022	11/02/2022	14/02/2022	18/02/2022	24/02/2022

	Deadline for Submission (*)	Start date (^)	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	PRAC outcome (~)	Comments from CAT and CHMP (**)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
C26	11/02/2022	23/02/2022	08/03/2022	28/02/2022	02/03/2022	03/03/2022	10/03/2022	11/03/2022	14/03/2022	18/03/2022	24/03/2022
C27	09/03/2022	21/03/2022	05/04/2022	28/03/2022	30/03/2022	31/03/2022	07/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
C28	08/04/2022	20/04/2022	03/05/2022	25/04/2022	26/04/2022	28/04/2022	05/05/2022	06/05/2022	10/05/2022	13/05/2022	19/05/2022
C29	13/05/2022	25/05/2022	07/06/2022	30/05/2022	01/06/2022	02/06/2022	10/05/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
C30	10/06/2022	22/06/2022	05/07/2022	27/06/2022	29/06/2022	30/06/2022	07/07/2022	08/07/2022	11/07/2022	15/07/2022	21/07/2022
C31											
C32	05/08/2022	17/08/2022	30/08/2022	22/08/2022	24/08/2022	25/08/2022	01/09/2022	02/09/2022	05/09/2022	09/09/2022	15/09/2022
C33	02/09/2022	14/09/2022	27/09/2022	19/09/2022	21/09/2022	22/09/2022	29/09/2022	30/09/2022	03/10/2022	07/10/2022	13/10/2022
C34	30/09/2022	12/10/2022	25/10/2022	17/10/2022	19/10/2022	20/10/2022	27/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
C35	04/11/2022	16/11/2022	29/11/2022	21/11/2022	23/11/2022	24/11/2022	01/12/2022	02/12/2022	05/12/2022	09/12/2022	15/12/2022
C36	01/12/2022	28/12/2022	10/01/2023	03/01/2023	04/01/2023	05/01/2023	12/01/2023	13/01/2023	16/01/2023	20/01/2023	26/01/2023
C37	13/01/2023	25/01/2023	07/02/2023	30/01/2023	01/02/2023	02/02/2023	09/02/2023	10/02/2023	13/02/2023	17/02/2023	23/02/2023
C38	17/02/2023	01/03/2023	14/03/2023	06/03/2023	08/03/2023	09/03/2023	16/03/2023	17/03/2023	20/03/2023	24/03/2023	30/03/2023
C39	17/03/2023	29/03/2023	11/04/2023	03/04/2023	04/04/2023	05/04/2023	14/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
C40	12/04/2023	24/04/2023	08/05/2023	02/05/2023	03/05/2023	04/05/2023	12/05/2023	12/05/2023	12/05/2023	17/05/2023	25/05/2023
C41	12/05/2023	24/05/2023	06/06/2023	30/05/2023	31/05/2023	01/06/2023	08/06/2023	09/06/2023	12/06/2023	16/06/2023	22/06/2023
C42	09/06/2023	21/06/2023	04/07/2023	26/06/2023	28/06/2023	29/06/2023	06/07/2023	07/07/2023	10/07/2023	14/07/2023	20/07/2023
C43											
C44	04/08/2023	16/08/2023	29/08/2023	21/08/2023	23/08/2023	24/08/2023	31/08/2023	01/09/2023	04/09/2023	08/09/2023	14/09/2023
C45	01/09/2023	13/09/2023	26/09/2023	18/09/2023	20/09/2023	21/09/2023	28/09/2023	29/09/2023	02/10/2023	06/10/2023	12/10/2023
C46	26/09/2023	08/10/2023	24/10/2023	16/10/2023	18/10/2023	19/10/2023	26/10/2023	27/10/2023	27/10/2023	31/10/2023	09/11/2023
C47	03/11/2023	15/11/2023	28/11/2023	20/11/2023	22/11/2023	23/11/2023	30/11/2023	01/12/2023	04/12/2023	08/12/2023	14/12/2023
C48	01/12/2023	27/12/2023	09/01/2024	03/01/2024	04/01/2024	05/01/2024	11/01/2024	12/01/2024	15/01/2024	19/01/2024	25/01/2024
C49	12/01/2024	24/01/2024	06/02/2024	29/01/2024	31/01/2024	01/02/2024	08/02/2024	09/02/2024	12/02/2024	16/02/2024	22/02/2024
C50	09/02/2024	21/02/2024	05/03/2024	26/02/2024	28/02/2024	29/02/2024	07/03/2024	08/03/2024	11/03/2024	15/03/2024	21/03/2024
C51	15/03/2024	27/03/2024	09/04/2024	02/04/2024	03/04/2024	04/04/2024	11/04/2024	12/04/2024	15/04/2024	19/04/2024	25/04/2024
C52	19/04/2024	01/05/2024	14/05/2024	06/05/2024	07/05/2024	08/05/2024	16/05/2024	17/05/2024	21/05/2024	24/05/2024	30/05/2024

	Deadline for Submission (*)	Start date (^)	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	PRAC outcome (~)	Comments from CAT and CHMP (**)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
C53	17/05/2024	29/05/2024	11/06/2024	03/06/2024	05/06/2024	06/06/2024	13/06/2024	14/06/2024	17/06/2024	21/06/2024	27/06/2024
C54	14/06/2024	26/06/2024	09/07/2024	01/07/2024	03/07/2024	04/07/2024	11/07/2024	12/07/2024	15/07/2024	19/07/2024	25/07/2024
C55											
C56	09/08/2024	21/08/2024	03/09/2024	26/08/2024	28/08/2024	29/08/2024	05/09/2024	06/09/2024	09/09/2024	13/09/2024	19/09/2024
C57	06/09/2024	18/09/2024	01/10/2024	23/09/2024	25/09/2024	26/09/2024	03/10/2024	04/10/2024	07/10/2024	11/10/2024	17/10/2024
C58	04/10/2024	16/10/2024	29/10/2024	21/10/2024	23/10/2024	24/10/2024	31/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
C59	31/10/2024	13/11/2024	26/11/2024	18/11/2024	20/11/2024	21/11/2024	28/11/2024	29/11/2024	02/12/2024	06/12/2024	12/12/2024

(-) This timetable applies to the initial assessment of relatively urgent safety variations agreed upfront to be assessed in a short timeframe.

(^) The validation period between submission date and start date is usually eleven calendar days.

(*) 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.

(~) Step applicable only in case of PRAC involvement (typically if RMP or results of non-interventional Post-Authorisation Safety Study (PASS) are submitted).

(**) Comments from CHMP and PRAC members are not made available to Applicants.

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

(#) Step applicable only in case of CAT Opinion (not applicable in case a Request for Supplementary Information is adopted by the CAT).

60-day responses (after clockstop) to RSI assessment timetable⁷

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR (!)	CAT Rapporteur AR (~)	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
D1	20/01/2020	21/01/2020	25/02/2020	21/02/2020	27/02/2020	03/03/2020	05/03/2020	10/03/2020	12/03/2020	16/03/2020	20/03/2020	26/03/2020
D2	24/02/2020	25/02/2020	31/03/2020	27/03/2020	02/04/2020	07/04/2020	08/04/2020	15/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
D3	20/03/2020	22/03/2020	27/04/2020	24/04/2020	30/04/2020	05/05/2020	07/05/2020	12/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
D4	20/04/2020	21/04/2020	26/05/2020	20/05/2020	28/05/2020	02/06/2020	04/06/2020	09/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
D5	18/05/2020	19/05/2020	23/06/2020	19/06/2020	25/06/2020	30/06/2020	02/07/2020	07/07/2020	09/07/2020	13/07/2020	17/07/2020	23/07/2020
D6												
D7	13/07/2020	14/07/2020	18/08/2020	14/08/2020	20/08/2020	25/08/2020	27/08/2020	02/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
D8	10/08/2020	11/08/2020	15/09/2020	11/09/2020	17/09/2020	22/09/2020	24/09/2020	29/09/2020	01/10/2020	05/10/2020	09/10/2020	15/10/2020
D9	07/09/2020	08/09/2020	13/10/2020	09/10/2020	15/10/2020	20/10/2020	22/10/2020	27/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020
D10	05/10/2020	06/10/2020	10/11/2020	06/11/2020	12/11/2020	17/11/2020	19/11/2020	24/11/2020	26/11/2020	30/11/2020	04/12/2020	10/12/2020
D11	23/11/2020	24/11/2020	04/01/2021	22/12/2020	04/01/2021	05/01/2021	07/01/2021	12/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
D12	21/12/2020	22/12/2020	26/01/2021	22/01/2021	28/01/2021	02/02/2021	04/02/2021	09/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
D13	18/01/2021	19/01/2021	23/02/2021	19/02/2021	25/02/2021	02/03/2021	04/03/2021	09/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
D14	15/02/2021	16/02/2021	23/03/2021	19/03/2021	25/03/2021	30/03/2021	31/03/2021	07/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
D15	12/03/2021	14/03/2021	19/04/2021	16/04/2021	22/04/2021	27/04/2021	29/04/2021	04/05/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
D16	19/04/2021	20/04/2021	25/05/2021	21/05/2021	27/05/2021	01/06/2021	03/06/2021	08/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
D17	17/05/2021	18/05/2021	22/06/2021	18/06/2021	24/06/2021	29/06/2021	01/07/2021	06/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
D18												
D19	12/07/2021	13/07/2021	17/08/2021	13/08/2021	19/08/2021	24/08/2021	26/08/2021	01/09/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
D20	09/08/2021	10/08/2021	14/09/2021	10/09/2021	16/09/2021	21/09/2021	23/09/2021	28/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
D21	06/09/2021	07/09/2021	12/10/2021	08/10/2021	14/10/2021	19/10/2021	21/10/2021	26/10/2021	28/10/2021	29/10/2021	05/11/2021	11/11/2021
D22	11/10/2021	12/10/2021	16/11/2021	12/11/2021	18/11/2021	23/11/2021	25/11/2021	30/11/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
D23	22/11/2021	23/11/2021	22/12/2021	21/12/2021	03/01/2022	05/01/2022	06/01/2022	11/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
D24	20/12/2021	21/12/2021	25/01/2022	21/01/2022	27/01/2022	01/02/2022	03/02/2022	08/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR (!)	CAT Rapporteur AR (~)	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
D25	17/01/2022	18/01/2022	22/02/2022	18/02/2022	24/02/2022	01/03/2022	03/03/2022	08/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
D26	11/02/2022	13/02/2022	22/03/2022	18/03/2022	24/03/2022	29/03/2022	31/03/2022	05/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
D27	14/03/2022	15/03/2022	19/04/2022	13/04/2022	21/04/2022	26/04/2022	28/04/2022	03/05/2022	05/05/2022	06/05/2022	13/05/2022	19/05/2022
D28	13/04/2022	19/04/2022	24/05/2022	20/05/2022	25/05/2022	31/05/2022	02/06/2022	07/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
D29	16/05/2022	17/05/2022	21/06/2022	17/06/2022	23/06/2022	28/06/2022	30/06/2022	05/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
D30												
D31	11/07/2022	12/07/2022	16/08/2022	12/08/2022	18/08/2022	23/08/2022	25/08/2022	30/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
D32	08/08/2022	09/08/2022	13/09/2022	09/09/2022	15/09/2022	20/09/2022	22/09/2022	27/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
D33	05/09/2022	06/09/2022	11/10/2022	07/10/2022	13/10/2022	18/10/2022	20/10/2022	25/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
D34	10/10/2022	11/10/2022	15/11/2022	11/11/2022	17/11/2022	22/11/2022	24/11/2022	29/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
D35	21/11/2022	22/11/2022	22/12/2022	22/12/2022	03/01/2023	04/01/2023	05/01/2023	10/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
D36	19/12/2022	20/12/2022	24/01/2023	20/01/2023	26/01/2023	31/01/2023	02/02/2023	07/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
D37	23/01/2023	24/01/2023	28/02/2023	24/02/2023	02/03/2023	07/03/2023	09/03/2023	14/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
D38	20/02/2023	21/02/2023	28/03/2023	24/03/2023	30/03/2023	04/04/2023	05/04/2023	11/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
D39	17/03/2023	19/03/2023	25/04/2023	21/04/2023	28/04/2023	02/05/2023	03/05/2023	08/05/2023	11/05/2023	12/05/2023	17/05/2023	25/05/2023
D40	17/04/2023	18/04/2023	23/05/2023	17/05/2023	25/05/2023	30/05/2023	01/06/2023	06/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
D41	15/05/2023	16/05/2023	20/06/2023	16/06/2023	22/06/2023	27/06/2023	29/06/2023	04/07/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
D42												
D43	10/07/2023	11/07/2023	14/08/2023	11/08/2023	17/08/2023	22/08/2023	24/08/2023	29/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
D44	07/08/2023	08/08/2023	12/09/2023	08/09/2023	14/09/2023	19/09/2023	21/09/2023	26/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
D45	01/09/2023	02/09/2023	10/10/2023	06/10/2023	12/10/2023	17/10/2023	19/10/2023	24/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
D46	09/10/2023	10/10/2023	14/11/2023	10/11/2023	16/11/2023	21/11/2023	23/11/2023	28/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
D47	20/11/2023	21/11/2023	21/12/2023	21/12/2023	03/01/2024	04/01/2024	05/01/2024	09/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
D48	18/12/2023	19/12/2023	23/01/2024	19/01/2024	25/01/2024	30/01/2024	01/02/2024	06/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
D49	15/01/2024	16/01/2024	20/02/2024	16/02/2024	22/02/2024	27/02/2024	29/02/2024	05/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
D50	19/02/2024	20/02/2024	26/03/2024	22/03/2024	27/03/2024	02/04/2024	04/04/2024	09/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR (!)	CAT Rapporteur AR (~)	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
D51	25/03/2024	26/03/2024	30/04/2024	26/04/2024	02/05/2024	07/05/2024	08/05/2024	14/05/2024	16/05/2024	17/05/2024	24/05/2024	30/05/2024
D52	22/04/2024	23/04/2024	28/05/2024	24/05/2024	30/05/2024	04/06/2024	06/06/2024	11/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
D53	17/05/2024	21/05/2024	25/06/2024	21/06/2024	27/06/2024	02/07/2024	04/07/2024	09/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
D54												
D55	15/07/2024	16/07/2024	20/08/2024	16/08/2024	22/08/2024	27/08/2024	29/08/2024	03/09/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
D56	12/08/2024	13/08/2024	17/09/2024	13/09/2024	19/09/2024	24/09/2024	26/09/2024	01/10/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
D57	09/09/2024	10/09/2024	15/10/2024	11/10/2024	17/10/2024	22/10/2024	24/10/2024	29/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
D58	07/10/2024	08/10/2024	12/11/2024	08/11/2024	14/11/2024	19/11/2024	21/11/2024	26/11/2024	28/11/2024	02/12/2024	06/12/2024	12/12/2024

(~) The timeframe for assessment of responses depends on the complexity and amount of data provided by the Marketing Authorisation Holder.

(*) 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.

(!) Step applicable if the PRAC is not involved (i.e. no RMP or or results of non-interventional Post-Authorisation Safety Study (PASS) are submitted).

(~) Step applicable only if the submission falls (at least partially) under the remit of the PRAC (typically, when a RMP is submitted). For PRAC-led variations (including only an RMP or final results of non-interventional PASS with no consequences to Product Information), only the PRAC Rapporteur produces an AR.

(**) Comments from CAT, CHMP and PRAC members are not made available to Applicants.

(***) An updated AR is optional and dependent on the comments received from committee (PRAC, CAT, CHMP) members which create the need for the update.

(#) Step applicable only in case of CAT Opinion (not applicable in case a Request for Supplementary Information is adopted by the CAT).

30-day responses (after clockstop) to RSI assessment timetable⁷

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
E1	22/01/2020	23/01/2020	06/02/2020	30/01/2020	04/02/2020	06/02/2020	12/02/2020	13/02/2020	17/02/2020	21/02/2020	27/02/2020
E2	19/02/2020	20/02/2020	05/03/2020	27/02/2020	03/03/2020	05/03/2020	11/03/2020	12/03/2020	16/03/2020	20/03/2020	26/03/2020
E3	25/03/2020	26/03/2020	08/04/2020	02/04/2020	07/04/2020	08/04/2020	15/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
E4	20/04/2020	21/04/2020	07/05/2020	30/04/2020	05/05/2020	07/05/2020	13/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
E5	20/05/2020	21/05/2020	04/06/2020	28/05/2020	02/06/2020	04/06/2020	10/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
E6	17/06/2020	18/06/2020	02/07/2020	25/06/2020	30/06/2020	02/07/2020	08/07/2020	09/07/2020	13/07/2020	17/07/2020	23/07/2020
E7											
E8	12/08/2020	13/08/2020	27/08/2020	20/08/2020	25/08/2020	27/08/2020	02/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
E9	09/09/2020	10/09/2020	24/09/2020	17/09/2020	22/09/2020	24/09/2020	30/09/2020	01/10/2020	05/10/2020	09/10/2020	15/10/2020
E10	07/10/2020	08/10/2020	22/10/2020	15/10/2020	20/10/2020	22/10/2020	28/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020
E11	04/11/2020	05/11/2020	19/11/2020	12/11/2020	17/11/2020	19/11/2020	25/11/2020	26/11/2020	30/11/2020	04/12/2020	10/12/2020
E12	23/12/2020	24/12/2020	07/01/2021	04/01/2021	06/01/2021	07/01/2021	13/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
E13	20/01/2021	21/01/2021	04/02/2021	28/01/2021	02/02/2021	04/02/2021	10/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
E14	17/02/2021	18/02/2021	04/03/2021	25/02/2021	02/03/2021	04/03/2021	10/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
E15	17/03/2021	18/03/2021	30/03/2021	25/03/2021	29/03/2021	30/03/2021	07/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
E16	12/04/2021	13/04/2021	29/04/2021	22/04/2021	27/04/2021	29/04/2021	05/05/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
E17	19/05/2021	20/05/2021	03/06/2021	27/05/2021	01/06/2021	03/06/2021	09/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
E18	16/06/2021	17/06/2021	01/07/2021	24/06/2021	29/06/2021	01/07/2021	07/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
E19											
E20	11/08/2021	12/08/2021	26/08/2021	19/08/2021	24/08/2021	26/08/2021	01/09/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
E21	08/09/2021	09/09/2021	23/09/2021	16/09/2021	21/09/2021	23/09/2021	29/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
E22	06/10/2021	07/10/2021	21/10/2021	14/10/2021	19/10/2021	21/10/2021	27/10/2021	28/10/2021	29/10/2021	05/11/2021	11/11/2021
E23	10/11/2021	11/11/2021	25/11/2021	18/11/2021	23/11/2021	25/11/2021	01/12/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
E24	22/12/2021	23/12/2021	06/01/2022	03/01/2022	04/01/2022	06/01/2022	12/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
E25	19/01/2022	20/01/2022	03/02/2022	27/01/2022	01/02/2022	03/02/2022	09/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
E26	16/02/2022	17/02/2022	03/03/2022	24/02/2022	01/03/2022	03/03/2022	09/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
E27	14/03/2022	15/03/2022	31/03/2022	24/03/2022	29/03/2022	31/03/2022	06/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
E28	13/04/2022	14/04/2022	28/04/2022	21/04/2022	26/04/2022	28/04/2022	04/05/2022	05/05/2022	10/05/2022	13/05/2022	19/05/2022
E29	18/05/2022	19/05/2022	02/06/2022	25/05/2022	31/05/2022	02/06/2022	08/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
E30	15/06/2022	16/06/2022	30/06/2022	23/06/2022	28/06/2022	30/06/2022	06/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
E31											
E32	10/08/2022	11/08/2022	25/08/2022	18/08/2022	23/08/2022	25/08/2022	31/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
E33	07/09/2022	08/09/2022	22/09/2022	15/09/2022	20/09/2022	22/09/2022	28/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
E34	05/10/2022	06/10/2022	20/10/2022	13/10/2022	18/10/2022	20/10/2022	26/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
E35	09/11/2022	10/11/2022	24/11/2022	17/11/2022	22/11/2022	24/11/2022	30/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
E36	21/12/2022	22/12/2022	05/01/2023	03/01/2023	04/01/2023	05/01/2023	11/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
E37	18/01/2023	19/01/2023	02/02/2023	26/01/2023	31/01/2023	02/02/2023	08/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
E38	22/02/2023	23/02/2023	09/03/2023	02/03/2023	07/03/2023	09/03/2023	15/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
E39	22/03/2023	23/03/2023	05/04/2023	30/03/2023	04/04/2023	05/04/2023	12/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
E40	17/04/2023	18/04/2023	04/05/2023	26/04/2023	02/05/2023	04/05/2023	10/05/2023	12/05/2023	12/05/2023	17/05/2023	25/05/2023
E41	17/05/2023	18/05/2023	01/06/2023	25/05/2023	30/05/2023	01/06/2023	07/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
E42	14/06/2023	15/06/2023	29/06/2023	22/06/2023	27/06/2023	29/06/2023	05/07/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
E43											
E44	09/08/2023	10/08/2023	24/08/2023	17/08/2023	22/08/2023	24/08/2023	30/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
E45	06/09/2023	07/09/2023	21/09/2023	14/09/2023	19/09/2023	21/09/2023	27/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
E46	29/09/2023	02/10/2023	19/10/2023	12/10/2023	17/10/2023	19/10/2023	25/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
E47	08/11/2023	09/11/2023	23/11/2023	16/11/2023	21/11/2023	23/11/2023	29/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
E48	20/12/2023	21/12/2023	04/01/2024	03/01/2024	04/01/2024	04/01/2024	10/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
E49	17/01/2024	18/01/2024	01/02/2024	25/01/2024	30/01/2024	01/02/2024	07/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
E50	14/02/2024	15/02/2024	29/02/2024	22/02/2024	27/02/2024	29/02/2024	06/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
E51	20/03/2024	21/03/2024	04/04/2024	27/03/2024	02/04/2024	04/04/2024	10/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024
E52	24/04/2024	25/04/2024	08/05/2024	02/05/2024	07/05/2024	08/05/2024	15/05/2024	16/05/2024	21/05/2024	24/05/2024	30/05/2024

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	PRAC outcome (~)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
E53	22/05/2024	23/05/2024	06/06/2024	30/05/2024	04/06/2024	06/06/2024	12/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
E54	19/06/2024	20/06/2024	04/07/2024	27/06/2024	02/07/2024	04/07/2024	10/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
E55											
E56	14/08/2024	15/08/2024	29/08/2024	22/08/2024	27/08/2024	29/08/2024	04/09/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
E57	11/09/2024	12/09/2024	26/09/2024	19/09/2024	24/09/2024	26/09/2024	02/10/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
E58	09/10/2024	10/10/2024	24/10/2024	17/10/2024	22/10/2024	24/10/2024	30/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
E59	06/11/2024	07/11/2024	21/11/2024	14/11/2024	19/11/2024	21/11/2024	27/11/2024	28/11/2024	02/12/2024	06/12/2024	12/12/2024

(-) The timeframe for assessment of responses depends on the complexity and amount of data provided by the Marketing Authorisation Holder.

(*) 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.

(~) Step applicable only if the submission falls (at least partially) under the remit of the PRAC (typically, when a RMP is submitted). For PRAC-led variations (including only an RMP or final results of non-interventional PASS with no consequences to Product Information), only the PRAC Rapporteur produces an AR.

(**) Comments from CHMP and PRAC members are not made available to Applicants.

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

(#) Step applicable only in case of CAT Opinion (not applicable in case a Request for Supplementary Information is adopted by the CAT).

30-day immediate responses to RSI assessment timetable⁷

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
F1	30/01/2020	31/01/2020	11/02/2020	11/02/2020	14/02/2020	17/02/2020	14/02/2020	17/02/2020	21/02/2020	27/02/2020
F2	27/02/2020	28/02/2020	10/03/2020	10/03/2020	13/03/2020	16/03/2020	13/03/2020	16/03/2020	20/03/2020	26/03/2020
F3	27/03/2020	30/03/2020	14/04/2020	14/04/2020	17/04/2020	20/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
F4	28/04/2020	29/04/2020	11/05/2020	11/05/2020	13/05/2020	15/05/2020	13/05/2020	15/05/2020	20/05/2020	28/05/2020
F5	28/05/2020	29/05/2020	09/06/2020	09/06/2020	12/06/2020	15/06/2020	12/06/2020	15/06/2020	19/06/2020	25/06/2020
F6	25/06/2020	26/06/2020	07/07/2020	07/07/2020	10/07/2020	13/07/2020	10/07/2020	13/07/2020	17/07/2020	23/07/2020
F7										
F8	20/08/2020	21/08/2020	01/09/2020	01/09/2020	04/09/2020	07/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
F9	17/09/2020	18/09/2020	29/09/2020	29/09/2020	02/10/2020	05/10/2020	02/10/2020	05/10/2020	09/10/2020	15/10/2020
F10	15/10/2020	16/10/2020	27/10/2020	27/10/2020	30/10/2020	03/11/2020	30/10/2020	03/11/2020	06/11/2020	12/11/2020
F11	12/11/2020	13/11/2020	24/11/2020	24/11/2020	27/11/2020	30/11/2020	27/11/2020	30/11/2020	04/12/2020	10/12/2020
F12	23/12/2020	25/12/2020	12/01/2021	12/01/2021	15/01/2021	18/01/2021	15/01/2021	18/01/2021	22/01/2021	28/01/2021
F13	28/01/2021	29/01/2021	09/02/2021	09/02/2021	12/02/2021	15/02/2021	12/02/2021	15/02/2021	19/02/2021	25/02/2021
F14	25/02/2021	26/02/2021	09/03/2021	09/03/2021	12/03/2021	15/03/2021	12/03/2021	15/03/2021	19/03/2021	25/03/2021
F15	25/03/2021	26/03/2021	06/04/2021	06/04/2021	09/04/2021	12/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
F16	20/04/2021	21/04/2021	03/05/2021	03/05/2021	05/05/2021	07/05/2021	05/05/2021	07/05/2021	12/05/2021	20/05/2021
F17	21/05/2021	25/05/2021	08/06/2021	08/06/2021	11/06/2021	14/06/2021	11/06/2021	14/06/2021	18/06/2021	24/06/2021
F18	24/06/2021	25/06/2021	06/07/2021	06/07/2021	09/07/2021	12/07/2021	09/07/2021	12/07/2021	16/07/2021	22/07/2021
F19										
F20	19/08/2021	20/08/2021	31/08/2021	31/08/2021	03/09/2021	06/09/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
F21	16/09/2021	17/09/2021	28/09/2021	28/09/2021	01/10/2021	04/10/2021	01/10/2021	04/10/2021	08/10/2021	14/10/2021
F22	14/10/2021	15/10/2021	26/10/2021	26/10/2021	29/10/2021	29/10/2021	29/10/2021	29/10/2021	05/11/2021	11/11/2021
F23	12/11/2021	15/11/2021	30/11/2021	30/11/2021	03/12/2021	06/12/2021	03/12/2021	06/12/2021	10/12/2021	16/12/2021
F24	22/12/2021	23/12/2021	11/01/2022	11/01/2022	14/01/2022	17/01/2022	14/01/2022	17/01/2022	21/01/2022	27/01/2022
F25	27/01/2022	28/01/2022	08/02/2022	08/02/2022	11/02/2022	14/02/2022	11/02/2022	14/02/2022	18/02/2022	24/02/2022

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
F26	24/02/2022	25/02/2022	08/03/2022	08/03/2022	11/03/2022	14/03/2022	11/03/2022	14/03/2022	18/03/2022	24/03/2022
F27	22/03/2022	23/03/2022	04/04/2022	04/04/2022	06/04/2022	08/04/2022	06/04/2022	08/04/2022	13/04/2022	22/04/2022
F28	21/04/2022	22/04/2022	03/05/2022	03/05/2022	06/05/2022	10/05/2022	06/05/2022	10/05/2022	13/05/2022	19/05/2022
F29	20/05/2022	23/05/2022	07/06/2022	07/06/2022	10/06/2022	13/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
F30	23/06/2022	24/06/2022	05/07/2022	05/07/2022	08/07/2022	11/07/2022	08/07/2022	11/07/2022	15/07/2022	21/07/2022
F31										
F32	10/08/2022	11/08/2022	30/08/2022	30/08/2022	02/09/2022	05/09/2022	02/09/2022	05/09/2022	09/09/2022	15/09/2022
F33	15/09/2022	16/09/2022	27/09/2022	27/09/2022	30/09/2022	03/10/2022	30/09/2022	03/10/2022	07/10/2022	13/10/2022
F34	13/10/2022	14/10/2022	25/10/2022	25/10/2022	27/10/2022	28/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
F35	11/11/2022	14/11/2022	29/11/2022	29/11/2022	02/12/2022	05/12/2022	02/12/2022	05/12/2022	09/12/2022	15/12/2022
F36	21/12/2022	22/12/2022	10/01/2023	10/01/2023	13/01/2023	16/01/2023	13/01/2023	16/01/2023	20/01/2023	26/01/2023
F37	26/01/2023	27/01/2023	07/02/2023	07/02/2023	10/02/2023	13/02/2023	10/02/2023	13/02/2023	17/02/2023	23/02/2023
F38	24/02/2023	27/02/2023	14/03/2023	14/03/2023	17/03/2023	20/03/2023	17/03/2023	20/03/2023	24/03/2023	30/03/2023
F39	30/03/2023	31/03/2023	11/04/2023	11/04/2023	14/04/2023	17/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
F40	25/04/2023	26/04/2023	08/05/2023	08/05/2023	10/05/2023	12/05/2023	10/05/2023	12/05/2023	17/05/2023	25/05/2023
F41	25/05/2023	26/05/2023	06/06/2023	06/06/2023	09/06/2023	12/06/2023	09/06/2023	12/06/2023	16/06/2023	22/06/2023
F42	22/06/2023	23/06/2023	04/07/2023	04/07/2023	07/07/2023	10/07/2023	07/07/2023	10/07/2023	14/07/2023	20/07/2023
F43										
F44	09/08/2023	10/08/2023	29/08/2023	29/08/2023	01/09/2023	04/09/2023	01/09/2023	04/09/2023	08/09/2023	14/09/2023
F45	14/09/2023	15/09/2023	26/09/2023	26/09/2023	29/09/2023	02/10/2023	29/09/2023	02/10/2023	06/10/2023	12/10/2023
F46	09/10/2023	10/10/2023	20/10/2023	20/10/2023	24/10/2023	27/10/2023	24/10/2023	27/10/2023	31/10/2023	09/11/2023
F47	08/11/2023	09/11/2023	28/11/2023	28/11/2023	01/12/2023	04/12/2023	01/12/2023	04/12/2023	08/12/2023	14/12/2023
F48	20/12/2023	21/12/2023	09/01/2024	09/01/2024	12/01/2024	15/01/2024	12/01/2024	15/01/2024	19/01/2024	25/01/2024
F49	25/01/2024	26/01/2024	06/02/2024	06/02/2024	09/02/2024	12/02/2024	09/02/2024	12/02/2024	16/02/2024	22/02/2024
F50	22/02/2024	23/02/2024	05/03/2024	05/03/2024	08/03/2024	11/03/2024	08/03/2024	11/03/2024	15/03/2024	21/03/2024
F51	22/03/2024	25/03/2024	09/04/2024	09/04/2024	12/04/2024	15/04/2024	12/04/2024	15/04/2024	19/04/2024	25/04/2024
F52	26/04/2024	29/04/2024	14/05/2024	14/05/2024	17/05/2024	21/05/2024	17/05/2024	21/05/2024	24/05/2024	30/05/2024

	Deadline for Submission (*)	Re-start date	CAT Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	Comments from CAT and CHMP (**)	Updated CAT Rapporteur AR (***)	CAT Request for Supplementary Information (RSI) or Opinion	CHMP Opinion (#)
F53	30/05/2024	31/05/2024	11/06/2024	11/06/2024	14/06/2024	17/06/2024	14/06/2024	17/06/2024	21/06/2024	27/06/2024
F54	27/06/2024	28/06/2024	09/07/2024	09/07/2024	12/07/2024	15/07/2024	12/07/2024	15/07/2024	19/07/2024	25/07/2024
F55										
F56	14/08/2024	15/08/2024	03/09/2024	03/09/2024	06/09/2024	09/09/2024	06/09/2024	09/09/2024	13/09/2024	19/09/2024
F57	19/09/2024	20/09/2024	01/10/2024	01/10/2024	04/10/2024	07/10/2024	04/10/2024	07/10/2024	11/10/2024	17/10/2024
F58	17/10/2024	18/10/2024	29/10/2024	29/10/2024	31/10/2024	04/11/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
F59	14/11/2024	15/11/2024	26/11/2024	26/11/2024	29/11/2024	02/12/2024	29/11/2024	02/12/2024	06/12/2024	12/12/2024

(-) This timetable is only applicable when minor issues remain and, if the variation involves the PRAC, a PRAC plenary discussion is not needed.

(*) 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.

(~) Step applicable only if the submission falls (at least partially) under the remit of the PRAC (typically, when a RMP is submitted). For PRAC-led variations (including only an RMP or final results of non-interventional PASS with no consequences to Product Information), only the PRAC Rapporteur produces an AR.

(**) Comments from CAT, CHMP and PRAC members are not made available to Applicants.

(***) An updated AR is optional and dependent on the comments received from committee (PRAC, CAT, CHMP) members which create the need for the update.

(#) Step applicable only in case of CAT Opinion (not applicable in case a Request for Supplementary Information is adopted by the CAT).