

24 November 2017
EMA/727192/2017
Human Medicines Evaluation

[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	12/10/2016	29/10/2016	23/12/2016	03/01/2017	04/01/2017	05/01/2017	10/01/2017	12/01/2017	16/01/2017	20/01/2017	26/01/2017
A2	09/11/2016	26/11/2016	20/01/2017	27/01/2017	01/02/2017	02/02/2017	07/02/2017	09/02/2017	13/02/2017	17/02/2017	23/02/2017
A3	07/12/2016	24/12/2016	17/02/2017	24/02/2017	01/03/2017	02/03/2017	07/03/2017	09/03/2017	13/03/2017	17/03/2017	23/03/2017
A4	05/01/2017	22/01/2017	18/03/2017	24/03/2017	29/03/2017	30/03/2017	31/03/2017	06/04/2017	07/04/2017	12/04/2017	21/04/2017
A5	01/02/2017	18/02/2017	12/04/2017	21/04/2017	26/04/2017	27/04/2017	02/05/2017	05/05/2017	08/05/2017	12/05/2017	18/05/2017
A6	08/03/2017	25/03/2017	19/05/2017	26/05/2017	31/05/2017	01/06/2017	06/06/2017	09/06/2017	12/06/2017	16/06/2017	22/06/2017
A7	05/04/2017	22/04/2017	16/06/2017	23/06/2017	28/06/2017	29/06/2017	04/07/2017	06/07/2017	10/07/2017	14/07/2017	20/07/2017
A8											
A9	31/05/2017	17/06/2017	11/08/2017	18/08/2017	23/08/2017	24/08/2017	29/08/2017	01/09/2017	04/09/2017	08/09/2017	14/09/2017
A10	28/06/2017	15/07/2017	08/09/2017	15/09/2017	20/09/2017	21/09/2017	26/09/2017	28/09/2017	02/10/2017	06/10/2017	12/10/2017
A11	26/07/2017	12/08/2017	06/10/2017	13/10/2017	18/10/2017	19/10/2017	20/10/2017	26/10/2017	27/10/2017	31/10/2017	09/11/2017
A12	30/08/2017	16/09/2017	10/11/2017	17/11/2017	22/11/2017	23/11/2017	28/11/2017	30/11/2017	04/12/2017	08/12/2017	14/12/2017
A13	11/10/2017	28/10/2017	22/12/2017	03/01/2018	04/01/2018	05/01/2018	09/01/2018	11/01/2018	15/01/2018	19/01/2018	25/01/2018
A14	08/11/2017	25/11/2017	19/01/2018	26/01/2018	31/01/2018	01/02/2018	06/02/2018	08/02/2018	12/02/2018	16/02/2018	22/02/2018
A15	29/11/2017	23/12/2017	16/02/2018	23/02/2018	28/02/2018	01/03/2018	06/03/2018	08/03/2018	12/03/2018	16/03/2018	22/03/2018
A16	10/01/2018	27/01/2018	23/03/2018	28/03/2018	04/04/2018	05/04/2018	10/04/2018	12/04/2018	16/04/2018	20/04/2018	26/04/2018
A17	14/02/2018	03/03/2018	27/04/2018	04/05/2018	07/05/2018	08/05/2018	15/05/2018	17/05/2018	22/05/2018	25/05/2018	31/05/2018
A18	14/03/2018	31/03/2018	25/05/2018	01/06/2018	06/06/2018	07/06/2018	12/06/2018	14/06/2018	18/06/2018	22/06/2018	28/06/2018
A19	11/04/2018	28/04/2018	22/06/2018	29/06/2018	04/07/2018	05/07/2018	10/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
A20											
A21	06/06/2018	23/06/2018	17/08/2018	24/08/2018	29/08/2018	30/08/2018	04/09/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
A22	04/07/2018	21/07/2018	14/09/2018	21/09/2018	26/09/2018	27/09/2018	02/10/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
A23	01/08/2018	18/08/2018	12/10/2018	19/10/2018	24/10/2018	25/10/2018	30/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
A24	29/08/2018	15/09/2018	09/11/2018	16/11/2018	21/11/2018	22/11/2018	27/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018

	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	17/10/2018	03/11/2018	20/12/2018	04/01/2019	09/01/2019	10/01/2019	15/01/2019	17/01/2019	21/01/2019	25/01/2019	31/01/2019
A26	14/11/2018	01/12/2018	25/01/2019	01/02/2019	06/02/2019	07/02/2019	12/02/2019	14/02/2019	18/02/2019	22/02/2019	28/02/2019
A27	28/11/2018	29/12/2018	22/02/2019	01/03/2019	06/03/2019	07/03/2019	12/03/2019	14/03/2019	18/03/2019	22/03/2019	28/03/2019
A28	07/01/2019	24/01/2019	20/03/2019	27/03/2019	01/04/2019	04/04/2019	08/04/2019	11/04/2019	12/04/2019	17/04/2019	26/04/2019
A29	13/02/2019	02/03/2019	26/04/2019	03/05/2019	07/05/2019	08/05/2019	14/05/2019	16/05/2019	20/05/2019	24/05/2019	29/05/2019
A30	13/03/2019	30/03/2019	23/05/2019	29/05/2019	05/06/2019	06/06/2019	11/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
A31	10/04/2019	27/04/2019	21/06/2019	28/06/2019	03/07/2019	04/07/2019	09/07/2019	11/07/2019	15/07/2019	19/07/2019	25/07/2019
A32											
A33	05/06/2019	22/06/2019	16/08/2019	23/08/2019	28/08/2019	29/08/2019	03/09/2019	05/09/2019	09/09/2019	13/09/2019	19/09/2019
A34	03/07/2019	20/07/2019	13/09/2019	20/09/2019	25/09/2019	26/09/2019	01/10/2019	03/10/2019	07/10/2019	11/10/2019	17/10/2019
A35	31/07/2019	17/08/2019	11/10/2019	18/10/2019	23/10/2019	24/10/2019	29/10/2019	31/10/2019	04/11/2019	08/11/2019	14/11/2019
A36	28/08/2019	14/09/2019	08/11/2019	15/11/2019	20/11/2019	21/11/2019	26/11/2019	28/11/2019	02/12/2019	06/12/2019	12/12/2019
A37	16/10/2019	02/11/2019	20/12/2019	03/01/2020	08/01/2020	09/01/2020	14/01/2020	16/01/2020	20/01/2020	24/01/2020	30/01/2020
A38	13/11/2019	30/11/2019	24/01/2020	31/01/2020	05/02/2020	06/02/2020	11/02/2020	13/02/2020	17/02/2020	21/02/2020	27/02/2020
A39	27/11/2019	28/12/2019	21/02/2020	28/02/2020	04/03/2020	05/03/2020	10/03/2020	12/03/2020	16/03/2020	20/03/2020	26/03/2020
A40	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
A41	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
A42	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
A43	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
A44											
A45	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
A46	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
A47	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
A48	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
A49	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
A50	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

	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	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
A52	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
A53	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
A54	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
A55	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
A56											
A57	02/06/2021	19/06/2021	13/08/2021	20/08/2021	25/08/2021	26/08/2021	31/08/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
A58	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
A59	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
A60	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

(-) 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 timetable ⁷

	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	11/11/2016	28/11/2016	03/01/2017	23/12/2016	03/01/2017	04/01/2017	05/01/2017	11/01/2017	12/01/2017	16/01/2017	20/01/2017	26/01/2017
B2	09/12/2016	26/12/2016	30/01/2017	24/01/2017	27/01/2017	01/02/2017	02/02/2017	08/02/2017	09/02/2017	13/02/2017	17/02/2017	23/02/2017
B3	06/01/2017	23/01/2017	27/02/2017	21/02/2017	24/02/2017	01/03/2017	02/03/2017	08/03/2017	09/03/2017	13/03/2017	17/03/2017	23/03/2017
B4	03/02/2017	21/02/2017	27/03/2017	22/03/2017	24/03/2017	29/03/2017	30/03/2017	03/04/2017	06/04/2017	07/04/2017	12/04/2017	21/04/2017
B5	03/03/2017	20/03/2017	24/04/2017	18/04/2017	21/04/2017	26/04/2017	27/04/2017	03/05/2017	05/05/2017	08/05/2017	12/05/2017	18/05/2017
B6	07/04/2017	24/04/2017	29/05/2017	23/05/2017	26/05/2017	31/05/2017	01/06/2017	07/06/2017	09/06/2017	12/06/2017	16/06/2017	22/06/2017
B7	05/05/2017	22/05/2017	26/06/2017	20/06/2017	23/06/2017	28/06/2017	29/06/2017	05/07/2017	06/07/2017	10/07/2017	14/07/2017	20/07/2017
B8												
B9	30/06/2017	17/07/2017	21/08/2017	15/08/2017	18/08/2017	23/08/2017	24/08/2017	30/08/2017	01/09/2017	04/09/2017	08/09/2017	14/09/2017
B10	28/07/2017	14/08/2017	18/09/2017	12/09/2017	15/09/2017	20/09/2017	21/09/2017	27/09/2017	28/09/2017	02/10/2017	06/10/2017	12/10/2017
B11	25/08/2017	11/09/2017	16/10/2017	10/10/2017	13/10/2017	18/10/2017	19/10/2017	22/10/2017	26/10/2017	27/10/2017	31/10/2017	09/11/2017
B12	29/09/2017	16/10/2017	20/11/2017	14/11/2017	17/11/2017	22/11/2017	23/11/2017	29/11/2017	30/11/2017	04/12/2017	08/12/2017	14/12/2017
B13	10/11/2017	27/11/2017	04/01/2018	22/12/2017	03/01/2018	04/01/2018	05/01/2018	10/01/2018	11/01/2018	15/01/2018	19/01/2018	25/01/2018
B14	29/11/2017	25/12/2017	29/01/2018	23/01/2018	26/01/2018	31/01/2018	01/02/2018	07/02/2018	08/02/2018	12/02/2018	16/02/2018	22/02/2018
B15	05/01/2018	22/01/2018	26/02/2018	20/02/2018	23/02/2018	28/02/2018	01/03/2018	07/03/2018	08/03/2018	12/03/2018	16/03/2018	22/03/2018
B16	09/02/2018	26/02/2018	02/04/2018	26/03/2018	28/03/2018	04/04/2018	05/04/2018	11/04/2018	12/04/2018	16/04/2018	20/04/2018	26/04/2018
B17	16/03/2018	02/04/2018	07/05/2018	30/04/2018	03/05/2018	07/05/2018	08/05/2018	16/05/2018	17/05/2018	22/05/2018	25/05/2018	31/05/2018
B18	13/04/2018	30/04/2018	04/06/2018	29/05/2018	01/06/2018	06/06/2018	07/06/2018	13/06/2018	14/06/2018	18/06/2018	22/06/2018	28/06/2018
B19	08/05/2018	28/05/2018	02/07/2018	26/06/2018	29/06/2018	04/07/2018	05/07/2018	11/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
B20												
B21	06/07/2018	23/07/2018	27/08/2018	21/08/2018	24/08/2018	29/08/2018	30/08/2018	05/09/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
B22	03/08/2018	20/08/2018	24/09/2018	18/09/2018	21/09/2018	26/09/2018	27/09/2018	03/10/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
B23	31/08/2018	17/09/2018	22/10/2018	16/10/2018	19/10/2018	24/10/2018	25/10/2018	31/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
B24	28/09/2018	15/10/2018	19/11/2018	13/11/2018	16/11/2018	21/11/2018	22/11/2018	28/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018

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B25	16/11/2018	03/12/2018	07/01/2019	20/12/2018	04/01/2019	09/01/2019	10/01/2019	16/01/2019	17/01/2019	21/01/2019	25/01/2019	31/01/2019
B26	30/11/2018	31/12/2018	04/02/2019	29/01/2019	01/02/2019	06/02/2019	07/02/2019	13/02/2019	14/02/2019	18/02/2019	22/02/2019	28/02/2019
B27	11/01/2019	28/01/2019	04/03/2019	26/02/2019	01/03/2019	06/03/2019	07/03/2019	13/03/2019	14/03/2019	18/03/2019	22/03/2019	28/03/2019
B28	06/02/2019	23/02/2019	01/04/2019	26/03/2019	29/03/2019	03/04/2019	04/04/2019	10/04/2019	11/04/2019	12/04/2019	17/04/2019	26/04/2019
B29	15/03/2019	01/04/2019	06/05/2019	30/04/2019	03/05/2019	07/05/2019	08/05/2019	15/05/2019	16/05/2019	20/05/2019	24/05/2019	29/05/2019
B30	12/04/2019	29/04/2019	03/06/2019	28/05/2019	03/06/2019	05/06/2019	06/06/2019	12/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
B31	10/05/2019	27/05/2019	01/07/2019	25/06/2019	28/06/2019	03/07/2019	04/07/2019	10/07/2019	11/07/2019	15/07/2019	19/07/2019	25/07/2019
B32												
B33	05/07/2019	22/07/2019	27/08/2019	20/08/2019	23/08/2019	28/08/2019	29/08/2019	04/09/2019	05/09/2019	09/09/2019	13/09/2019	19/09/2019
B34	02/08/2019	19/08/2019	23/09/2019	17/09/2019	20/09/2019	25/09/2019	26/09/2019	02/10/2019	03/10/2019	07/10/2019	11/10/2019	17/10/2019
B35	30/08/2019	16/09/2019	21/10/2019	15/10/2019	18/10/2019	23/10/2019	24/10/2019	30/10/2019	31/10/2019	04/11/2019	08/11/2019	14/11/2019
B36	27/09/2019	14/10/2019	18/11/2019	12/11/2019	15/11/2019	20/11/2019	21/11/2019	27/11/2019	28/11/2019	02/12/2019	06/12/2019	12/12/2019
B37	15/11/2019	02/12/2019	06/01/2020	20/12/2019	03/01/2020	08/01/2020	09/01/2020	15/01/2020	16/01/2020	20/01/2020	24/01/2020	30/01/2020
B38	29/11/2019	30/12/2019	03/02/2020	28/01/2020	31/01/2020	05/02/2020	06/02/2020	12/02/2020	13/02/2020	17/02/2020	21/02/2020	27/02/2020
B39	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
B40	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
B41	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
B42	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
B43	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
B44												
B45	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
B46	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
B47	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
B48	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
B49	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
B50	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

	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	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
B52	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
B53	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
B54	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
B55	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
B56												
B57	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
B58	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
B59	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
B60	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

(~) 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	16/12/2016	28/12/2016	10/01/2017	03/01/2017	04/01/2017	05/01/2017	12/01/2017	13/01/2017	16/01/2017	20/01/2017	26/01/2017
C2	13/01/2017	25/01/2017	07/02/2017	30/01/2017	01/02/2017	02/02/2017	09/02/2017	10/02/2017	13/02/2017	17/02/2017	23/02/2017
C3	10/02/2017	22/02/2017	07/03/2017	27/02/2017	01/03/2017	02/03/2017	09/03/2017	10/03/2017	13/03/2017	17/03/2017	23/03/2017
C4	10/03/2017	23/03/2017	03/04/2017	27/03/2017	29/03/2017	30/03/2017	06/04/2017	17/04/2017	07/04/2017	12/04/2017	21/04/2017
C5	07/04/2017	19/04/2017	02/05/2017	24/04/2017	26/04/2017	27/04/2017	05/05/2017	05/05/2017	08/05/2017	12/05/2017	18/05/2017
C6	12/05/2017	24/05/2017	06/06/2017	29/05/2017	31/05/2017	01/06/2017	09/06/2017	09/06/2017	12/06/2017	16/06/2017	22/06/2017
C7	09/06/2017	21/06/2017	04/07/2017	26/06/2017	28/06/2017	29/06/2017	06/07/2017	07/07/2017	10/07/2017	14/07/2017	20/07/2017
C8											
C9	04/08/2017	16/08/2017	29/08/2017	21/08/2017	23/08/2017	24/08/2017	01/09/2017	01/09/2017	04/09/2017	08/09/2017	14/09/2017
C10	01/09/2017	13/09/2017	26/09/2017	18/09/2017	20/09/2017	21/09/2017	28/09/2017	29/09/2017	02/10/2017	06/10/2017	12/10/2017
C11	29/09/2017	11/10/2017	23/10/2017	16/10/2017	18/10/2017	19/10/2017	26/10/2017	26/10/2017	27/10/2017	31/10/2017	09/11/2017
C12	03/11/2017	15/11/2017	28/11/2017	20/11/2017	22/11/2017	23/11/2017	30/11/2017	01/12/2017	04/12/2017	08/12/2017	14/12/2017
C13	01/12/2017	27/12/2017	09/01/2018	03/01/2018	04/01/2018	05/01/2018	11/01/2018	12/01/2018	15/01/2018	19/01/2018	25/01/2018
C14	12/01/2018	24/01/2018	06/02/2018	29/01/2018	31/01/2018	01/02/2018	08/02/2018	09/02/2018	12/02/2018	16/02/2018	22/02/2018
C15	09/02/2018	21/02/2018	06/03/2018	26/02/2018	28/02/2018	01/03/2018	08/03/2018	09/03/2018	12/03/2018	16/03/2018	22/03/2018
C16	16/03/2018	28/03/2018	10/04/2018	03/04/2018	04/04/2018	05/04/2018	12/04/2018	13/04/2018	16/04/2018	20/04/2018	26/04/2018
C17	20/04/2018	02/05/2018	15/05/2018	04/05/2018	07/05/2018	08/05/2018	17/05/2018	18/05/2018	22/05/2018	25/05/2018	31/05/2018
C18	18/05/2018	30/05/2018	12/06/2018	04/06/2018	06/06/2018	07/06/2018	14/06/2018	15/06/2018	18/06/2018	22/06/2018	28/06/2018
C19	15/06/2018	27/06/2018	10/07/2018	02/07/2018	04/07/2018	05/07/2018	12/07/2018	13/07/2018	16/07/2018	20/07/2018	26/07/2018
C20											
C21	10/08/2018	22/08/2018	04/09/2018	28/08/2018	29/08/2018	30/08/2018	06/09/2018	07/09/2018	10/09/2018	14/09/2018	20/09/2018
C22	07/09/2018	19/09/2018	02/10/2018	24/09/2018	26/09/2018	27/09/2018	04/10/2018	05/10/2018	08/10/2018	12/10/2018	18/10/2018
C23	05/10/2018	17/10/2018	29/10/2018	22/10/2018	24/10/2018	25/10/2018	31/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
C24	31/10/2018	14/11/2018	27/11/2018	19/11/2018	21/11/2018	22/11/2018	29/11/2018	30/11/2018	03/12/2018	07/12/2018	13/12/2018
C25	30/11/2018	02/01/2019	15/01/2019	07/01/2019	09/01/2019	10/01/2019	17/01/2019	18/01/2019	21/01/2019	25/01/2019	31/01/2019

	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	18/01/2019	30/01/2019	12/02/2019	04/02/2019	06/02/2019	07/02/2019	14/02/2019	15/02/2019	18/02/2019	22/02/2019	28/02/2019
C27	15/02/2019	27/02/2019	12/03/2019	04/03/2019	06/03/2019	07/03/2019	14/03/2019	15/03/2019	18/03/2019	22/03/2019	28/03/2019
C28	13/03/2019	25/03/2019	09/04/2019	01/04/2019	03/04/2019	04/04/2019	11/04/2019	11/04/2019	12/04/2019	17/04/2019	26/04/2019
C29	17/04/2019	01/05/2019	14/05/2019	06/05/2019	07/05/2019	08/05/2019	16/05/2019	17/05/2019	20/05/2019	24/05/2019	29/05/2019
C30	17/05/2019	29/05/2019	11/06/2019	03/06/2019	05/06/2019	06/06/2019	14/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
C31	14/06/2019	26/06/2019	09/07/2019	01/07/2019	03/07/2019	04/07/2019	11/07/2019	12/07/2019	15/07/2019	19/07/2019	25/07/2019
C32											
C33	09/08/2019	21/08/2019	03/09/2019	27/08/2019	28/08/2019	29/08/2019	05/09/2019	06/09/2019	09/09/2019	13/09/2019	19/09/2019
C34	06/09/2019	18/09/2019	01/10/2019	23/09/2019	25/09/2019	26/09/2019	03/10/2019	04/10/2019	07/10/2019	11/10/2019	17/10/2019
C35	04/10/2019	16/10/2019	29/10/2019	21/10/2019	23/10/2019	24/10/2019	31/10/2019	31/10/2019	04/11/2019	08/11/2019	14/11/2019
C36	31/10/2019	13/11/2019	26/11/2019	18/11/2019	20/11/2019	21/11/2019	28/11/2019	29/11/2019	02/12/2019	06/12/2019	12/12/2019
C37	29/11/2019	01/01/2020	14/01/2020	06/01/2020	08/01/2020	09/01/2020	16/01/2020	17/01/2020	20/01/2020	24/01/2020	30/01/2020
C38	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
C39	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
C40	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
C41	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
C42	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
C43	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
C44											
C45	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
C46	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
C47	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
C48	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
C49	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
C50	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
C51	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
C52	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

	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	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
C54	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
C55	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
C56											
C57	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
C58	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
C59	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
C60	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

(-) 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	16/01/2017	17/01/2017	21/02/2017	17/02/2017	23/02/2017	28/02/2017	02/03/2017	07/03/2017	09/03/2017	13/03/2017	17/03/2017	23/03/2017
D2	10/02/2017	12/02/2017	20/03/2017	15/03/2017	21/03/2017	28/03/2017	30/03/2017	03/04/2017	06/04/2017	07/04/2017	12/04/2017	21/04/2017
D3	13/03/2017	14/03/2017	18/04/2017	12/04/2017	20/04/2017	25/04/2017	27/04/2017	02/05/2017	05/05/2017	08/05/2017	12/05/2017	18/05/2017
D4	17/04/2017	18/04/2017	23/05/2017	19/05/2017	24/05/2017	30/05/2017	01/06/2017	06/06/2017	09/06/2017	12/06/2017	16/06/2017	22/06/2017
D5	15/05/2017	16/05/2017	20/06/2017	16/06/2017	22/06/2017	27/06/2017	29/06/2017	04/07/2017	06/07/2017	10/07/2017	14/07/2017	20/07/2017
D6												
D7	10/07/2017	11/07/2017	15/08/2017	11/08/2017	17/08/2017	22/08/2017	24/08/2017	29/08/2017	01/09/2017	04/09/2017	08/09/2017	14/09/2017
D8	07/08/2017	08/08/2017	12/09/2017	08/09/2017	14/09/2017	19/09/2017	21/09/2017	26/09/2017	28/09/2017	02/10/2017	06/10/2017	12/10/2017
D9	01/09/2017	02/09/2017	06/10/2017	03/10/2017	09/10/2017	17/10/2017	19/10/2017	23/10/2017	26/10/2017	27/10/2017	31/10/2017	09/11/2017
D10	09/10/2017	10/10/2017	14/11/2017	10/11/2017	16/11/2017	21/11/2017	23/11/2017	28/11/2017	30/11/2017	04/12/2017	08/12/2017	14/12/2017
D11	20/11/2017	21/11/2017	21/12/2017	22/12/2017	03/01/2018	04/01/2018	05/01/2018	09/01/2018	11/01/2018	15/01/2018	19/01/2018	25/01/2018
D12	18/12/2017	19/12/2017	23/01/2018	19/01/2018	25/01/2018	30/01/2018	01/02/2018	06/02/2018	08/02/2018	12/02/2018	16/02/2018	22/02/2018
D13	15/01/2018	16/01/2018	20/02/2018	16/02/2018	22/02/2018	27/02/2018	01/03/2018	06/03/2018	08/03/2018	12/03/2018	16/03/2018	22/03/2018
D14	19/02/2018	20/02/2018	27/03/2018	23/03/2018	28/03/2018	04/04/2018	05/04/2018	10/04/2018	12/04/2018	16/04/2018	20/04/2018	26/04/2018
D15	26/03/2018	27/03/2018	02/05/2018	27/04/2018	03/05/2018	07/05/2018	08/05/2018	15/05/2018	17/05/2018	22/05/2018	25/05/2018	31/05/2018
D16	23/04/2018	24/04/2018	29/05/2018	25/05/2018	31/05/2018	05/06/2018	07/06/2018	12/06/2018	14/06/2018	18/06/2018	22/06/2018	28/06/2018
D17	18/05/2018	22/05/2018	26/06/2018	22/06/2018	28/06/2018	03/07/2018	05/07/2018	10/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
D18												
D19	16/07/2018	17/07/2018	21/08/2018	17/08/2018	23/08/2018	28/08/2018	30/08/2018	04/09/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
D20	13/08/2018	14/08/2018	18/09/2018	14/09/2018	20/09/2018	25/09/2018	27/09/2018	02/10/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
D21	10/09/2018	11/09/2018	16/10/2018	12/10/2018	18/10/2018	23/10/2018	25/10/2018	30/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
D22	08/10/2018	09/10/2018	13/11/2018	09/11/2018	15/11/2018	20/11/2018	22/11/2018	27/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018
D23	26/11/2018	27/11/2018	03/01/2019	20/12/2018	03/01/2019	08/01/2019	10/01/2019	15/01/2019	17/01/2019	21/01/2019	25/01/2019	31/01/2019

	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 (#)
D24	21/12/2018	25/12/2018	29/01/2019	25/01/2019	31/01/2019	05/02/2019	07/02/2019	12/02/2019	14/02/2019	18/02/2019	22/02/2019	28/02/2019
D25	21/01/2019	22/01/2019	26/02/2019	22/02/2019	28/02/2019	05/03/2019	07/03/2019	12/03/2019	14/03/2019	18/03/2019	22/03/2019	28/03/2019
D26	15/02/2019	17/02/2019	26/03/2019	22/03/2019	28/03/2019	02/04/2019	04/04/2019	09/04/2019	11/04/2019	12/04/2019	17/04/2019	26/04/2019
D27	25/03/2019	26/03/2019	30/04/2019	26/04/2019	02/05/2019	07/05/2019	08/05/2019	14/05/2019	16/05/2019	20/05/2019	24/05/2019	29/05/2019
D28	17/04/2019	23/04/2019	28/05/2019	24/05/2019	29/05/2019	04/06/2019	06/06/2019	11/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
D29	20/05/2019	21/05/2019	25/06/2019	21/06/2019	27/06/2019	02/07/2019	04/07/2019	09/07/2019	11/07/2019	15/07/2019	19/07/2019	25/07/2019
D30												
D31	15/07/2019	16/07/2019	20/08/2019	16/08/2019	22/08/2019	27/08/2019	29/08/2019	03/09/2019	05/09/2019	09/09/2019	13/09/2019	19/09/2019
D32	12/08/2019	13/08/2019	17/09/2019	13/09/2019	19/09/2019	24/09/2019	26/09/2019	01/10/2019	03/10/2019	07/10/2019	11/10/2019	17/10/2019
D33	09/09/2019	10/09/2019	15/10/2019	11/10/2019	17/10/2019	22/10/2019	24/10/2019	29/10/2019	31/10/2019	04/11/2019	08/11/2019	14/11/2019
D34	07/10/2019	08/10/2019	12/11/2019	08/11/2019	14/11/2019	19/11/2019	21/11/2019	26/11/2019	28/11/2019	02/12/2019	06/12/2019	12/12/2019
D35	25/11/2019	26/11/2019	03/01/2020	20/12/2019	03/01/2020	07/01/2020	09/01/2020	14/01/2020	16/01/2020	20/01/2020	24/01/2020	30/01/2020
D36	23/12/2019	24/12/2019	28/01/2020	24/01/2020	30/01/2020	04/02/2020	06/02/2020	11/02/2020	13/02/2020	17/02/2020	21/02/2020	27/02/2020
D37	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
D38	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
D39	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
D40	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
D41	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
D42												
D43	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
D44	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
D45	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
D46	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
D47	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
D48	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

	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 (#)
D49	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
D50	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
D51	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
D52	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
D53	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
D54												
D55	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
D56	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
D57	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
D58	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

(~) 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 timetable¹

	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	18/01/2017	19/01/2017	02/02/2017	26/01/2017	31/01/2017	02/02/2017	08/02/2017	09/02/2017	13/02/2017	17/02/2017	23/02/2017
E2	15/02/2017	16/02/2017	02/03/2017	23/02/2017	28/02/2017	02/03/2017	08/03/2017	09/03/2017	13/03/2017	17/03/2017	23/03/2017
E3	13/03/2017	14/03/2017	28/03/2017	21/03/2017	27/03/2017	28/03/2017	03/04/2017	06/04/2017	07/04/2017	12/04/2017	21/04/2017
E4	12/04/2017	13/04/2017	27/04/2017	20/04/2017	25/04/2017	27/04/2017	03/05/2017	05/05/2017	08/05/2017	12/05/2017	18/05/2017
E5	17/05/2017	18/05/2017	01/06/2017	24/05/2017	30/05/2017	01/06/2017	07/06/2017	09/06/2017	12/06/2017	16/06/2017	22/06/2017
E6	14/06/2017	15/06/2017	29/06/2017	22/06/2017	27/06/2017	29/06/2017	05/07/2017	06/07/2017	10/07/2017	14/07/2017	20/07/2017
E7											
E8	09/08/2017	10/08/2017	24/08/2017	17/08/2017	22/08/2017	24/08/2017	30/08/2017	01/09/2017	04/09/2017	08/09/2017	14/09/2017
E9	06/09/2017	07/09/2017	21/09/2017	14/09/2017	19/09/2017	21/09/2017	27/09/2017	28/09/2017	02/10/2017	06/10/2017	12/10/2017
E10	29/09/2017	02/10/2017	16/10/2017	09/10/2017	13/10/2017	16/10/2017	22/10/2017	26/10/2017	27/10/2017	31/10/2017	09/11/2017
E11	08/11/2017	09/11/2017	23/11/2017	16/11/2017	21/11/2017	23/11/2017	29/11/2017	30/11/2017	04/12/2017	08/12/2017	14/12/2017
E12	20/12/2017	21/12/2017	05/01/2018	03/01/2018	04/01/2018	05/01/2018	10/01/2018	11/01/2018	15/01/2018	19/01/2018	25/01/2018
E13	17/01/2018	18/01/2018	01/02/2018	25/01/2018	30/01/2018	01/02/2018	07/02/2018	08/02/2018	12/02/2018	16/02/2018	22/02/2018
E14	14/02/2018	15/02/2018	01/03/2018	22/02/2018	27/02/2018	01/03/2018	07/03/2018	08/03/2018	12/03/2018	16/03/2018	22/03/2018
E15	21/03/2018	22/03/2018	05/04/2018	28/03/2018	03/04/2018	05/04/2018	11/04/2018	12/04/2018	16/04/2018	20/04/2018	26/04/2018
E16	25/04/2018	26/04/2018	08/05/2018	03/05/2018	07/05/2018	08/05/2018	16/05/2018	17/05/2018	22/05/2018	25/05/2018	31/05/2018
E17	23/05/2018	24/05/2018	07/06/2018	31/05/2018	05/06/2018	07/06/2018	13/06/2018	14/06/2018	18/06/2018	22/06/2018	28/06/2018
E18	20/06/2018	21/06/2018	05/07/2018	28/06/2018	03/07/2018	05/07/2018	11/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
E19											
E20	15/08/2018	16/08/2018	30/08/2018	23/08/2018	28/08/2018	30/08/2018	05/09/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
E21	12/09/2018	13/09/2018	27/09/2018	20/09/2018	25/09/2018	27/09/2018	03/10/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
E22	10/10/2018	11/10/2018	25/10/2018	18/10/2018	23/10/2018	25/10/2018	31/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
E23	07/11/2018	08/11/2018	22/11/2018	15/11/2018	20/11/2018	22/11/2018	28/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018
E24	21/12/2018	27/12/2018	10/01/2019	03/01/2019	08/01/2019	10/01/2019	16/01/2019	17/01/2019	21/01/2019	25/01/2019	31/01/2019

	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 (#)
E25	23/01/2019	24/01/2019	07/02/2019	31/01/2019	05/02/2019	07/02/2019	13/02/2019	14/02/2019	18/02/2019	22/02/2019	28/02/2019
E26	20/02/2019	21/02/2019	07/03/2019	28/02/2019	05/03/2019	07/03/2019	13/03/2019	14/03/2019	18/03/2019	22/03/2019	28/03/2019
E27	18/03/2019	19/03/2019	04/04/2019	28/03/2019	02/04/2019	04/04/2019	10/04/2019	11/04/2019	12/04/2019	17/04/2019	26/04/2019
E28	24/04/2019	25/04/2019	08/05/2019	02/05/2019	07/05/2019	08/05/2019	15/05/2019	16/05/2019	20/05/2019	24/05/2019	29/05/2019
E29	22/05/2019	23/05/2019	06/06/2019	29/05/2019	04/06/2019	06/06/2019	12/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
E30	19/06/2019	20/06/2019	04/07/2019	27/06/2019	02/07/2019	04/07/2019	10/07/2019	11/07/2019	15/07/2019	19/07/2019	25/07/2019
E31											
E32	14/08/2019	15/08/2019	29/08/2019	22/08/2019	27/08/2019	29/08/2019	04/09/2019	05/09/2019	09/09/2019	13/09/2019	19/09/2019
E33	11/09/2019	12/09/2019	26/09/2019	19/09/2019	24/09/2019	26/09/2019	02/10/2019	03/10/2019	07/10/2019	11/10/2019	17/10/2019
E34	09/10/2019	10/10/2019	24/10/2019	17/10/2019	22/10/2019	24/10/2019	30/10/2019	31/10/2019	04/11/2019	08/11/2019	14/11/2019
E35	06/11/2019	07/11/2019	21/11/2019	14/11/2019	19/11/2019	21/11/2019	27/11/2019	28/11/2019	02/12/2019	06/12/2019	12/12/2019
E36	23/12/2019	26/12/2019	09/01/2020	03/01/2020	07/01/2020	09/01/2020	15/01/2020	16/01/2020	20/01/2020	24/01/2020	30/01/2020
E37	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
E38	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
E39	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
E40	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
E41	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
E42	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
E43											
E44	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
E45	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
E46	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
E47	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
E48	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
E49	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
E50	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

	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 (#)
E51	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
E52	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
E53	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
E54	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
E55											
E56	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
E57	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
E58	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
E59	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

(~) 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	26/01/2017	27/01/2017	07/02/2017	07/02/2017	10/02/2017	10/02/2017	13/02/2017	13/02/2017	17/02/2017	23/02/2017
F2	23/02/2017	24/02/2017	07/03/2017	07/03/2017	10/03/2017	10/03/2017	13/03/2017	13/03/2017	17/03/2017	23/03/2017
F3	21/03/2017	22/03/2017	03/04/2017	03/04/2017	05/04/2017	05/04/2017	07/04/2017	07/04/2017	12/04/2017	21/04/2017
F4	20/04/2017	21/04/2017	02/05/2017	02/05/2017	05/05/2017	05/05/2017	08/05/2017	08/05/2017	12/05/2017	18/05/2017
F5	24/05/2017	26/05/2017	06/06/2017	06/06/2017	09/06/2017	09/06/2017	12/06/2017	12/06/2017	16/06/2017	22/06/2017
F6	22/06/2017	23/06/2017	04/07/2017	04/07/2017	07/07/2017	07/07/2017	10/07/2017	10/07/2017	14/07/2017	20/07/2017
F7										
F8										
F9	14/09/2017	15/09/2017	26/09/2017	26/09/2017	29/09/2017	29/09/2017	02/10/2017	02/10/2017	06/10/2017	12/10/2017
F10	09/10/2017	10/10/2017	20/10/2017	20/10/2017	24/10/2017	24/10/2017	27/10/2017	27/10/2017	31/10/2017	09/11/2017
F11	16/11/2017	17/11/2017	28/11/2017	28/11/2017	01/12/2017	01/12/2017	04/12/2017	04/12/2017	08/12/2017	14/12/2017
F12	22/12/2017	29/12/2017	09/01/2018	09/01/2018	12/01/2018	12/01/2018	15/01/2018	15/01/2018	19/01/2018	25/01/2018
F13	25/01/2018	26/01/2018	06/02/2018	06/02/2018	09/02/2018	09/02/2018	12/02/2018	12/02/2018	16/02/2018	22/02/2018
F14	22/02/2017	23/02/2018	06/03/2018	06/03/2018	09/03/2018	09/03/2018	12/03/2018	12/03/2018	16/03/2018	22/03/2018
F15	23/03/2018	26/03/2018	10/04/2018	10/04/2018	13/04/2018	13/04/2018	16/04/2018	16/04/2018	20/04/2018	26/04/2018
F16	27/04/2018	30/04/2018	15/05/2018	15/05/2018	18/05/2018	18/05/2018	22/05/2018	22/05/2018	25/05/2018	31/05/2018
F17	31/05/2018	01/06/2018	12/06/2018	12/06/2018	15/06/2018	15/06/2018	18/06/2018	18/06/2018	22/06/2018	28/06/2018
F18	28/06/2018	29/06/2018	10/07/2018	10/07/2018	13/07/2018	13/07/2018	16/07/2018	16/07/2018	20/07/2018	26/07/2018
F19										
F20										
F21	20/09/2018	21/09/2018	02/10/2018	02/10/2018	05/10/2018	05/10/2018	08/10/2018	08/10/2018	12/10/2018	18/10/2018
F22	18/10/2018	19/10/2018	30/10/2018	30/10/2018	31/10/2018	31/10/2018	05/11/2018	05/11/2018	09/11/2018	15/11/2018
F23	15/11/2018	16/11/2018	27/11/2018	27/11/2018	30/11/2018	30/11/2018	03/12/2018	03/12/2018	07/12/2018	13/12/2018
F24	21/12/2018	28/12/2018	15/01/2019	15/01/2019	18/01/2019	18/01/2019	21/01/2019	21/01/2019	25/01/2019	31/01/2019

	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 (#)
F25	31/01/2019	01/02/2019	12/02/2019	12/02/2019	15/02/2019	18/02/2019	15/02/2019	18/02/2019	22/02/2019	28/02/2019
F26	28/02/2019	01/03/2019	12/03/2019	12/03/2019	15/03/2019	18/03/2019	15/03/2019	18/03/2019	22/03/2019	28/03/2019
F27	26/03/2019	27/03/2019	08/04/2019	08/04/2019	10/04/2019	12/04/2019	10/04/2019	12/04/2019	17/04/2019	26/04/2019
F28	26/04/2019	29/04/2019	14/05/2019	14/05/2019	17/05/2019	20/05/2019	17/05/2019	20/05/2019	24/05/2019	29/05/2019
F29	29/05/2019	31/05/2019	11/06/2019	11/06/2019	14/06/2019	17/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
F30	27/06/2019	28/06/2019	09/07/2019	09/07/2019	12/07/2019	15/07/2019	12/07/2019	15/07/2019	19/07/2019	25/07/2019
F31										
F32										
F33	19/09/2019	20/09/2019	01/10/2019	01/10/2019	04/10/2019	07/10/2019	04/10/2019	07/10/2019	11/10/2019	17/10/2019
F34	17/10/2019	18/10/2019	29/10/2019	29/10/2019	30/10/2019	04/11/2019	30/10/2019	04/11/2019	08/11/2019	14/11/2019
F35	14/11/2019	15/11/2019	26/11/2019	26/11/2019	29/11/2019	02/12/2019	29/11/2019	02/12/2019	06/12/2019	12/12/2019
F36	23/12/2019	27/12/2019	14/01/2020	14/01/2020	17/01/2020	20/01/2020	17/01/2020	20/01/2020	24/01/2020	30/01/2020
F37	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
F38	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
F39	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
F40	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
F41	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
F42	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
F43										
F44										
F45	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
F46	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
F47	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
F48	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
F49	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
F50	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

	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 (#)
F51	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
F52	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
F53	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
F54	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
F55										
F56										
F57	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
F58	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
F59	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

(-) 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).