

1 March 2019
EMA/577385/2016 Rev.3
Human Medicines Evaluation

[The timetables in this document may be subject to revision](#)

Type II variation and worksharing application **monthly*** assessment timetables

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](#)

* monthly timetables have an outcome during the week of the CHMP meeting

90-day initial submission assessment timetable⁷

	Submission deadline (*)	Start date (^)	CHMP (Co-) Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
A1	05/01/2017	22/01/2017	17/03/2017	24/03/2017	29/03/2017	30/03/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
A2	01/02/2017	18/02/2017	12/04/2017	21/04/2017	26/04/2017	27/04/2017	05/05/2017	08/05/2017	11/05/2017	18/05/2017
A3	08/03/2017	25/03/2017	19/05/2017	26/05/2017	31/05/2017	01/06/2017	09/06/2017	12/06/2017	15/06/2017	22/06/2017
A4	05/04/2017	22/04/2017	16/06/2017	23/06/2017	28/06/2017	29/06/2017	06/07/2017	10/07/2017	13/07/2017	20/07/2017
A5										
A6	31/05/2017	17/06/2017	11/08/2017	18/08/2017	23/08/2017	24/08/2017	01/09/2017	04/09/2017	07/09/2017	14/09/2017
A7	28/06/2017	15/07/2017	08/09/2017	15/09/2017	20/09/2017	21/09/2017	28/09/2017	02/10/2017	05/10/2017	12/10/2017
A8	26/07/2017	12/08/2017	06/10/2017	13/10/2017	18/10/2017	19/10/2017	26/10/2017	30/10/2017	03/11/2017	09/11/2017
A9	30/08/2017	16/09/2017	10/11/2017	17/11/2017	22/11/2017	23/11/2017	30/11/2017	04/12/2017	07/12/2017	14/12/2017
A10	11/10/2017	28/10/2017	21/12/2017	03/01/2018	04/01/2018	05/01/2018	11/01/2018	15/01/2018	18/01/2018	25/01/2018
A11	08/11/2017	25/11/2017	19/01/2018	26/01/2018	31/01/2018	01/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
A12	29/11/2017	23/12/2017	16/02/2018	23/02/2018	28/02/2018	01/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
A13	10/01/2018	27/01/2018	23/03/2018	28/03/2018	04/04/2018	05/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
A14	14/02/2018	03/03/2018	27/04/2018	03/05/2018	07/05/2018	08/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
A15	14/03/2018	31/03/2018	25/05/2018	01/06/2018	06/06/2018	07/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
A16	11/04/2018	28/04/2018	22/06/2018	29/06/2018	04/07/2018	05/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
A17										
A18	06/06/2018	23/06/2018	17/08/2018	24/08/2018	29/08/2018	30/08/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
A19	04/07/2018	21/07/2018	14/09/2018	21/09/2018	26/09/2018	27/09/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
A20	01/08/2018	18/08/2018	12/10/2018	19/10/2018	24/10/2018	25/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
A21	29/08/2018	15/09/2018	09/11/2018	16/11/2018	21/11/2018	22/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
A22	17/10/2018	03/11/2018	20/12/2018	04/01/2019	09/01/2019	10/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019
A23	14/11/2018	01/12/2018	25/01/2019	01/02/2019	06/02/2019	07/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019
A24	28/11/2018	29/12/2018	22/02/2019	01/03/2019	06/03/2019	07/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019
A25	10/01/2019	27/01/2019	22/03/2019	29/03/2019	03/04/2019	04/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019

	Submission deadline (*)	Start date (^)	CHMP (Co-) Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
A26	12/02/2019	01/03/2019	25/04/2019	02/05/2019	07/05/2019	08/05/2019	16/05/2019	20/05/2019	23/05/2019	29/05/2019
A27	13/03/2019	30/03/2019	23/05/2019	29/05/2019	05/06/2019	06/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
A28	10/04/2019	27/04/2019	21/06/2019	28/06/2019	03/07/2019	04/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
A29										
A30	05/06/2019	22/06/2019	16/08/2019	23/08/2019	28/08/2019	29/08/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
A31	03/07/2019	20/07/2019	13/09/2019	20/09/2019	25/09/2019	26/09/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
A32	31/07/2019	17/08/2019	11/10/2019	18/10/2019	23/10/2019	24/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
A33	28/08/2019	14/09/2019	08/11/2019	15/11/2019	20/11/2019	21/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
A34	16/10/2019	02/11/2019	20/12/2019	03/01/2020	08/01/2020	09/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
A35	13/11/2019	30/11/2019	24/01/2020	31/01/2020	05/02/2020	06/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
A36	27/11/2019	28/12/2019	21/02/2020	28/02/2020	04/03/2020	05/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
A37	15/01/2020	01/02/2020	27/03/2020	02/04/2020	06/04/2020	07/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
A38	12/02/2020	29/02/2020	24/04/2020	30/04/2020	06/05/2020	07/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
A39	11/03/2020	28/03/2020	20/05/2020	29/05/2020	03/06/2020	04/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
A40	08/04/2020	25/04/2020	19/06/2020	26/06/2020	01/07/2020	02/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
A41										
A42	03/06/2020	20/06/2020	14/08/2020	21/08/2020	26/08/2020	27/08/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
A43	01/07/2020	18/07/2020	11/09/2020	18/09/2020	23/09/2020	24/09/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
A44	29/07/2020	15/08/2020	09/10/2020	16/10/2020	21/10/2020	22/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
A45	26/08/2020	12/09/2020	06/11/2020	13/11/2020	18/11/2020	19/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
A46	14/10/2020	31/10/2020	22/12/2020	04/01/2021	06/01/2021	07/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
A47	11/11/2020	28/11/2020	22/01/2021	29/01/2021	03/02/2021	04/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
A48	25/11/2020	26/12/2020	19/02/2021	26/02/2021	03/03/2021	04/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
A49	06/01/2021	23/01/2021	19/03/2021	25/03/2021	29/03/2021	30/03/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
A50	03/02/2021	20/02/2021	16/04/2021	23/04/2021	28/04/2021	29/04/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
A51	10/03/2021	27/03/2021	21/05/2021	28/05/2021	02/06/2021	03/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
A52	07/04/2021	24/04/2021	18/06/2021	25/06/2021	30/06/2021	01/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021

	Submission deadline (*)	Start date (^)	CHMP (Co-) Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
A53										
A54	02/06/2021	19/06/2021	13/08/2021	20/08/2021	25/08/2021	26/08/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
A55	30/06/2021	17/07/2021	10/09/2021	17/09/2021	22/09/2021	23/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
A56	28/07/2021	14/08/2021	08/10/2021	15/10/2021	20/10/2021	21/10/2021	28/10/2021	29/10/2021	04/11/2021	11/11/2021
A57	01/09/2021	18/09/2021	12/11/2021	19/11/2021	24/11/2021	25/11/2021	02/12/2021	06/12/2021	09/12/2021	16/12/2021

(-) This timetable is only applicable to the initial assessment of variations concerning a change to or addition of therapeutic indications and occasionally of grouped variations agreed by the Agency. Changes of existing indications (and rarely additions of new indications) may exceptionally follow a 60-day timetable, if supported by limited additional data. A 90-day initial timetable for a grouped variation or a 60-day initial timetable for an indication change (rarely, for new indication) should be agreed with the Agency at the time of validation of the application.

(^) The validation period between initial submission 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 partially falls under the remit of the PRAC (typically, when a RMP is 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.

60-day initial submission assessment timetable⁷

	Submission deadline (*)	Start date (^)	CHMP Rapporteur AR (if PRAC is not involved)	Steps only applicable in case of PRAC involvement					Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
				CHMP Rapporteur AR	PRAC Rapporteur AR	Comments from PRAC (**)	Updated PRAC Rapporteur AR (***)	PRAC outcome			
B1	06/01/2017	23/01/2017	27/02/2017	21/02/2017	24/02/2017	01/03/2017	02/03/2017	09/03/2017	13/03/2017	16/03/2017	23/03/2017
B2	03/02/2017	21/02/2017	27/03/2017	22/03/2017	24/03/2017	29/03/2017	30/03/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
B3	03/03/2017	20/03/2017	24/04/2017	18/04/2017	21/04/2017	26/04/2017	27/04/2017	05/05/2017	08/05/2017	11/05/2017	18/05/2017
B4	07/04/2017	24/04/2017	29/05/2017	23/05/2017	26/05/2017	31/05/2017	01/06/2017	09/06/2017	12/06/2017	15/06/2017	22/06/2017
B5	05/05/2017	22/05/2017	26/06/2017	20/06/2017	23/06/2017	28/06/2017	29/06/2017	06/07/2017	10/07/2017	13/07/2017	20/07/2017
B6											
B7	30/06/2017	17/07/2017	21/08/2017	15/08/2017	18/08/2017	23/08/2017	24/08/2017	01/09/2017	04/09/2017	07/09/2017	14/09/2017
B8	28/07/2017	14/08/2017	18/09/2017	12/09/2017	15/09/2017	20/09/2017	21/09/2017	28/09/2017	02/10/2017	05/10/2017	12/10/2017
B9	25/08/2017	11/09/2017	16/10/2017	10/10/2017	13/10/2017	18/10/2017	19/10/2017	26/10/2017	30/10/2017	03/11/2017	09/11/2017
B10	29/09/2017	16/10/2017	20/11/2017	14/11/2017	17/11/2017	22/11/2017	23/11/2017	30/11/2017	04/12/2017	07/12/2017	14/12/2017
B11	10/11/2017	27/11/2017	03/01/2018	21/12/2017	03/01/2018	04/01/2018	05/01/2018	11/01/2018	15/01/2018	18/01/2018	25/01/2018
B12	29/11/2017	25/12/2017	29/01/2018	23/01/2018	26/01/2018	31/01/2018	01/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
B13	05/01/2018	22/01/2018	26/02/2018	20/02/2018	23/02/2018	28/02/2018	01/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
B14	09/02/2018	26/02/2018	03/04/2018	26/03/2018	28/03/2018	04/04/2018	05/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
B15	16/03/2018	02/04/2018	07/05/2018	30/04/2018	04/05/2018	07/05/2018	08/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
B16	13/04/2018	30/04/2018	04/06/2018	29/05/2018	01/06/2018	06/06/2018	07/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
B17	08/05/2018	28/05/2018	02/07/2018	26/06/2018	29/06/2018	04/07/2018	05/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
B18											
B19	06/07/2018	23/07/2018	28/08/2018	21/08/2018	24/08/2018	29/08/2018	30/08/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
B20	03/08/2018	20/08/2018	24/09/2018	18/09/2018	21/09/2018	26/09/2018	27/09/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
B21	31/08/2018	17/09/2018	22/10/2018	16/10/2018	19/10/2018	24/10/2018	25/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
B22	28/09/2018	15/10/2018	19/11/2018	13/11/2018	16/11/2018	21/11/2018	22/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
B23	16/11/2018	03/12/2018	07/01/2019	20/12/2018	04/01/2019	09/01/2019	10/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019
B24	30/11/2018	31/12/2018	04/02/2019	29/01/2019	01/02/2019	06/02/2019	07/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019
B25	11/01/2019	28/01/2019	04/03/2019	26/02/2019	01/03/2019	06/03/2019	07/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019

	Submission deadline (*)	Start date (^)	CHMP Rapporteur AR (if PRAC is not involved)	Steps only applicable in case of PRAC involvement					Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
				CHMP Rapporteur AR	PRAC Rapporteur AR	Comments from PRAC (**)	Updated PRAC Rapporteur AR (***)	PRAC outcome			
B26	08/02/2019	26/02/2019	01/04/2019	26/03/2019	29/03/2019	03/04/2019	04/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
B27	14/03/2019	31/03/2019	06/05/2019	29/04/2019	02/05/2019	07/05/2019	08/05/2019	16/05/2019	20/05/2019	23/05/2019	29/05/2019
B28	12/04/2019	29/04/2019	03/06/2019	28/05/2019	03/06/2019	05/06/2019	06/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
B29	10/05/2019	27/05/2019	01/07/2019	25/06/2019	28/06/2019	03/07/2019	04/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
B30											
B31	05/07/2019	22/07/2019	27/08/2019	20/08/2019	23/08/2019	28/08/2019	29/08/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
B32	02/08/2019	19/08/2019	23/09/2019	17/09/2019	20/09/2019	25/09/2019	26/09/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
B33	30/08/2019	16/09/2019	21/10/2019	15/10/2019	18/10/2019	23/10/2019	24/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
B34	27/09/2019	14/10/2019	18/11/2019	12/11/2019	15/11/2019	20/11/2019	21/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
B35	15/11/2019	02/12/2019	06/01/2020	20/12/2019	03/01/2020	08/01/2020	09/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
B36	29/11/2019	30/12/2019	03/02/2020	28/01/2020	31/01/2020	05/02/2020	06/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
B37	10/01/2020	27/01/2020	02/03/2020	25/02/2020	28/02/2020	04/03/2020	05/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
B38	14/02/2020	02/03/2020	06/04/2020	31/03/2020	03/04/2020	07/04/2020	08/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
B39	13/03/2020	30/03/2020	04/05/2020	28/04/2020	30/04/2020	06/05/2020	07/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
B40	08/04/2020	27/04/2020	02/06/2020	26/05/2020	29/05/2020	03/06/2020	04/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
B41	08/05/2020	25/05/2020	29/06/2020	23/06/2020	26/06/2020	01/07/2020	02/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
B42											
B43	03/07/2020	20/07/2020	24/08/2020	18/08/2020	21/08/2020	26/08/2020	27/08/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
B44	31/07/2020	17/08/2020	21/09/2020	15/09/2020	18/09/2020	23/09/2020	24/09/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
B45	28/08/2020	14/09/2020	19/10/2020	13/10/2020	16/10/2020	21/10/2020	22/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
B46	25/09/2020	12/10/2020	16/11/2020	10/11/2020	13/11/2020	18/11/2020	19/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
B47	13/11/2020	30/11/2020	04/01/2021	22/12/2020	04/01/2021	06/01/2021	07/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
B48	27/11/2020	28/12/2020	01/02/2021	26/01/2021	29/01/2021	03/02/2021	04/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
B49	08/01/2021	25/01/2021	01/03/2021	23/02/2021	26/02/2021	03/03/2021	04/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
B50	05/02/2021	22/02/2021	29/03/2021	23/03/2021	26/03/2021	30/03/2021	31/03/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
B51	05/03/2021	22/03/2021	26/04/2021	20/04/2021	23/04/2021	28/04/2021	29/04/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
B52	09/04/2021	26/04/2021	31/05/2021	25/05/2021	28/05/2021	02/06/2021	03/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021

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				CHMP Rapporteur AR	PRAC Rapporteur AR	Comments from PRAC (**)	Updated PRAC Rapporteur AR (***)	PRAC outcome			
B53	07/05/2021	24/05/2021	28/06/2021	22/06/2021	25/06/2021	30/06/2021	01/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
B54											
B55	02/07/2021	19/07/2021	23/08/2021	17/08/2021	20/08/2021	25/08/2021	26/08/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
B56	30/07/2021	16/08/2021	20/09/2021	14/09/2021	17/09/2021	22/09/2021	23/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
B57	27/08/2021	13/09/2021	18/10/2021	12/10/2021	15/10/2021	20/10/2021	21/10/2021	28/10/2021	29/10/2021	04/11/2021	11/11/2021
B58	01/10/2021	18/10/2021	22/11/2021	16/11/2021	19/11/2021	24/11/2021	25/11/2021	02/12/2021	06/12/2021	09/12/2021	16/12/2021

(–) This timetable applies to variations leading to immediate EC Decision; these are mainly variations for new contraindications, for changes in posology or variations with a DHPC, as well as variations for addition of or changes to indications although these typically follow a 90-days timetable. The timetable also applies to variations requiring or expected to require a CHMP discussion.

(*) 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.

(^) For procedures with a 60-day initial assessment, the validation period between initial submission and start date is usually sixteen calendar days.

(**) 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.

30-day initial submission assessment timetable⁷

	Submission deadline (*)	Start date (^)	PRAC Rapporteur AR (~)	Comments from PRAC (**)(~)	Updated PRAC Rapporteur AR (***)(~)	CHMP Rapporteur AR	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
C1	13/01/2017	25/01/2017	30/01/2017	01/02/2017	02/02/2017	08/02/2017	09/02/2017	13/02/2017	16/02/2017	23/02/2017
C2	10/02/2017	22/02/2017	27/02/2017	01/03/2017	02/03/2017	08/03/2017	09/03/2017	13/03/2017	16/03/2017	23/03/2017
C3	10/03/2017	23/03/2017	27/03/2017	29/03/2017	30/03/2017	06/04/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
C4	07/04/2017	19/04/2017	24/04/2017	26/04/2017	27/04/2017	03/05/2017	05/05/2017	08/05/2017	11/05/2017	18/05/2017
C5	12/05/2017	24/05/2017	29/05/2017	31/05/2017	01/06/2017	07/06/2017	09/06/2017	12/06/2017	15/06/2017	22/06/2017
C6	09/06/2017	21/06/2017	26/06/2017	28/06/2017	29/06/2017	05/07/2017	06/07/2017	10/07/2017	13/07/2017	20/07/2017
C7										
C8	04/08/2017	16/08/2017	21/08/2017	23/08/2017	24/08/2017	30/08/2017	01/09/2017	04/09/2017	07/09/2017	14/09/2017
C9	01/09/2017	13/09/2017	18/09/2017	20/09/2017	21/09/2017	27/09/2017	28/09/2017	02/10/2017	05/10/2017	12/10/2017
C10	29/09/2017	11/10/2017	16/10/2017	18/10/2017	19/10/2017	25/10/2017	26/10/2017	30/10/2017	03/11/2017	09/11/2017
C11	03/11/2017	15/11/2017	20/11/2017	22/11/2017	23/11/2017	29/11/2017	30/11/2017	04/12/2017	07/12/2017	14/12/2017
C12	01/12/2017	27/12/2017	03/01/2018	04/01/2018	05/01/2018	10/01/2018	11/01/2018	15/01/2018	18/01/2018	25/01/2018
C13	12/01/2018	24/01/2018	29/01/2018	31/01/2018	01/02/2018	07/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
C14	09/02/2018	21/02/2018	26/02/2018	28/02/2018	01/03/2018	07/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
C15	16/03/2018	28/03/2018	03/04/2018	04/04/2018	05/04/2018	11/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
C16	20/04/2018	02/05/2018	04/05/2018	07/05/2018	08/05/2018	16/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
C17	18/05/2018	30/05/2018	04/06/2018	06/06/2018	07/06/2018	13/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
C18	15/06/2018	27/06/2018	02/07/2018	04/07/2018	05/07/2018	11/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
C19										
C20	10/08/2018	22/08/2018	28/08/2018	29/08/2018	30/08/2018	05/09/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
C21	07/09/2018	19/09/2018	24/09/2018	26/09/2018	27/09/2018	03/10/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
C22	05/10/2018	17/10/2018	22/10/2018	24/10/2018	25/10/2018	31/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
C23	31/10/2018	14/11/2018	19/11/2018	21/11/2018	22/11/2018	28/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
C24	30/11/2018	02/01/2019	07/01/2019	09/01/2019	10/01/2019	16/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019
C25	18/01/2019	30/01/2019	04/02/2019	06/02/2019	07/02/2019	13/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019

	Submission deadline (*)	Start date (^)	PRAC Rapporteur AR (~)	Comments from PRAC (**)(~)	Updated PRAC Rapporteur AR (***)(~)	CHMP Rapporteur AR	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
C26	15/02/2019	27/02/2019	04/03/2019	06/03/2019	07/03/2019	13/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019
C27	13/03/2019	28/03/2019	01/04/2019	03/04/2019	04/04/2019	10/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
C28	17/04/2019	30/04/2019	06/05/2019	07/05/2019	08/05/2019	15/05/2019	16/05/2019	20/05/2019	23/05/2019	29/05/2019
C29	17/05/2019	29/05/2019	03/06/2019	05/06/2019	06/06/2019	12/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
C30	14/06/2019	26/06/2019	01/07/2019	03/07/2019	04/07/2019	10/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
C31										
C32	09/08/2019	21/08/2019	27/08/2019	28/08/2019	29/08/2019	04/09/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
C33	06/09/2019	18/09/2019	23/09/2019	25/09/2019	26/09/2019	02/10/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
C34	04/10/2019	16/10/2019	21/10/2019	23/10/2019	24/10/2019	30/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
C35	31/10/2019	13/11/2019	18/11/2019	20/11/2019	21/11/2019	27/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
C36	29/11/2019	01/01/2020	06/01/2020	08/01/2020	09/01/2020	15/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
C37	17/01/2020	29/01/2020	03/02/2020	05/02/2020	06/02/2020	12/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
C38	14/02/2020	26/02/2020	02/03/2020	04/03/2020	05/03/2020	11/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
C39	20/03/2020	01/04/2020	06/04/2020	07/04/2020	08/04/2020	15/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
C40	15/04/2020	29/04/2020	04/05/2020	06/05/2020	07/05/2020	13/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
C41	15/05/2020	27/05/2020	29/05/2020	03/06/2020	04/06/2020	10/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
C42	12/06/2020	24/06/2020	29/06/2020	01/07/2020	02/07/2020	08/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
C43										
C44	07/08/2020	19/08/2020	24/08/2020	26/08/2020	27/08/2020	02/09/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
C45	04/09/2020	16/09/2020	21/09/2020	23/09/2020	24/09/2020	30/09/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
C46	02/10/2020	14/10/2020	19/10/2020	21/10/2020	22/10/2020	28/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
C47	30/10/2020	11/11/2020	16/11/2020	18/11/2020	19/11/2020	25/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
C48	27/11/2020	30/12/2020	04/01/2021	06/01/2021	07/01/2021	13/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
C49	15/01/2021	27/01/2021	01/02/2021	03/02/2021	04/02/2021	10/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
C50	12/02/2021	24/02/2021	01/03/2021	03/03/2021	04/03/2021	10/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
C51	12/03/2021	24/03/2021	29/03/2021	30/03/2021	31/03/2021	07/04/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
C52	07/04/2021	21/04/2021	26/04/2021	28/04/2021	29/04/2021	05/05/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021

	Submission deadline (*)	Start date (^)	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	CHMP Rapporteur AR	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
C53	12/05/2021	26/05/2021	31/05/2021	02/06/2021	03/06/2021	09/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
C54	11/06/2021	23/06/2021	28/06/2021	30/06/2021	01/07/2021	07/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
C55										
C56	06/08/2021	18/08/2021	23/08/2021	25/08/2021	26/08/2021	01/09/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
C57	03/09/2021	15/09/2021	20/09/2021	22/09/2021	23/09/2021	29/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
C58	01/10/2021	13/10/2021	18/10/2021	20/10/2021	21/10/2021	27/10/2021	28/10/2021	03/11/2021	05/11/2021	11/11/2021
C59	05/11/2021	17/11/2021	22/11/2021	24/11/2021	25/11/2021	01/12/2021	02/12/2021	06/12/2021	09/12/2021	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 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 initial submission and start date is usually eleven calendar days.

(~) Step applicable only if the PRAC is involved in the assessment phase (typically, for the assessment of an RMP or a non-interventional PASS).

(**) 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.

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

	Submission deadline (*)	Re-start date	CHMP Rapporteur AR (if PRAC is not involved)	Steps only applicable in case of PRAC involvement					Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
				CHMP Rapporteur AR	PRAC Rapporteur AR	Comments from PRAC (**)	Updated PRAC Rapporteur AR (***)	PRAC outcome			
D1	20/01/2017	23/01/2017	27/02/2017	21/02/2017	24/02/2017	01/03/2017	02/03/2017	09/03/2017	13/03/2017	16/03/2017	23/03/2017
D2	17/02/2017	21/02/2017	27/03/2017	22/03/2017	24/03/2017	29/03/2017	30/03/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
D3	17/03/2017	20/03/2017	24/04/2017	18/04/2017	21/04/2017	26/04/2017	27/04/2017	05/05/2017	08/05/2017	11/05/2017	18/05/2017
D4	21/04/2017	24/04/2017	29/05/2017	23/05/2017	26/05/2017	31/05/2017	01/06/2017	09/06/2017	12/06/2017	15/06/2017	22/06/2017
D5	19/05/2017	22/05/2017	26/06/2017	20/06/2017	23/06/2017	28/06/2017	29/06/2017	06/07/2017	10/07/2017	13/07/2017	20/07/2017
D6											
D7	14/07/2017	17/07/2017	21/08/2017	15/08/2017	18/08/2017	23/08/2017	24/08/2017	01/09/2017	04/09/2017	07/09/2017	14/09/2017
D8	11/08/2017	14/08/2017	18/09/2017	12/09/2017	15/09/2017	20/09/2017	21/09/2017	28/09/2017	02/10/2017	05/10/2017	12/10/2017
D9	08/09/2017	11/09/2017	16/10/2017	10/10/2017	13/10/2017	18/10/2017	19/10/2017	26/10/2017	30/10/2017	03/11/2017	09/11/2017
D10	13/10/2017	16/10/2017	20/11/2017	14/11/2017	17/11/2017	22/11/2017	23/11/2017	30/11/2017	04/12/2017	07/12/2017	14/12/2017
D11	24/11/2017	27/11/2017	03/01/2018	21/12/2017	03/01/2018	04/01/2018	05/01/2018	11/01/2018	15/01/2018	18/01/2018	25/01/2018
D12	22/12/2017	25/12/2017	29/01/2018	23/01/2018	26/01/2018	31/01/2018	01/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
D13	19/01/2018	22/01/2018	26/02/2018	20/02/2018	23/02/2018	28/02/2018	01/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
D14	23/02/2018	26/02/2018	03/04/2018	26/03/2018	28/03/2018	04/04/2018	05/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
D15	28/03/2018	02/04/2018	07/05/2018	30/04/2018	04/05/2018	07/05/2018	08/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
D16	27/04/2018	30/04/2018	04/06/2018	29/05/2018	01/06/2018	06/06/2018	07/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
D17	25/05/2018	28/05/2018	02/07/2018	26/06/2018	29/06/2018	04/07/2018	05/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
D18											
D19	20/07/2018	23/07/2018	28/08/2018	21/08/2018	24/08/2018	29/08/2018	30/08/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
D20	17/08/2018	20/08/2018	24/09/2018	18/09/2018	21/09/2018	26/09/2018	27/09/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
D21	14/09/2018	17/09/2018	22/10/2018	16/10/2018	19/10/2018	24/10/2018	25/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
D22	12/10/2018	15/10/2018	19/11/2018	13/11/2018	16/11/2018	21/11/2018	22/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
D23	30/11/2018	03/12/2018	07/01/2019	20/12/2018	04/01/2019	09/01/2019	10/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019
D24	21/12/2018	31/12/2018	04/02/2019	29/01/2019	01/02/2019	06/02/2019	07/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019

	Submission deadline (*)	Re-start date	CHMP Rapporteur AR (if PRAC is not involved)	Steps only applicable in case of PRAC involvement					Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
				CHMP Rapporteur AR	PRAC Rapporteur AR	Comments from PRAC (**)	Updated PRAC Rapporteur AR (***)	PRAC outcome			
D25	25/01/2019	28/01/2019	04/03/2019	26/02/2019	01/03/2019	06/03/2019	07/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019
D26	22/02/2019	26/02/2019	01/04/2019	26/03/2019	29/03/2019	03/04/2019	04/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
D27	29/03/2019	31/03/2019	06/05/2019	29/04/2019	02/05/2019	07/05/2019	08/05/2019	16/05/2019	20/05/2019	23/05/2019	29/05/2019
D28	26/04/2019	29/04/2019	03/06/2019	28/05/2019	03/06/2019	05/06/2019	06/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
D29	24/05/2019	27/05/2019	01/07/2019	25/06/2019	28/06/2019	03/07/2019	04/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
D30											
D31	19/07/2019	22/07/2019	27/08/2019	20/08/2019	23/08/2019	28/08/2019	29/08/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
D32	16/08/2019	19/08/2019	23/09/2019	17/09/2019	20/09/2019	25/09/2019	26/09/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
D33	13/09/2019	16/09/2019	21/10/2019	15/10/2019	18/10/2019	23/10/2019	24/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
D34	11/10/2019	14/10/2019	18/11/2019	12/11/2019	15/11/2019	20/11/2019	21/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
D35	29/11/2019	02/12/2019	06/01/2020	20/12/2019	03/01/2020	08/01/2020	09/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
D36	23/12/2019	30/12/2019	03/02/2020	28/01/2020	31/01/2020	05/02/2020	06/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
D37	24/01/2020	27/01/2020	02/03/2020	25/02/2020	28/02/2020	04/03/2020	05/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
D38	28/02/2020	02/03/2020	06/04/2020	31/03/2020	03/04/2020	07/04/2020	08/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
D39	27/03/2020	30/03/2020	04/05/2020	28/04/2020	30/04/2020	06/05/2020	07/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
D40	24/04/2020	27/04/2020	02/06/2020	26/05/2020	29/05/2020	03/06/2020	04/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
D41	20/05/2020	25/05/2020	29/06/2020	23/06/2020	26/06/2020	01/07/2020	02/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
D42											
D43	17/07/2020	20/07/2020	24/08/2020	18/08/2020	21/08/2020	26/08/2020	27/08/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
D44	14/08/2020	17/08/2020	21/09/2020	15/09/2020	18/09/2020	23/09/2020	24/09/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
D45	11/09/2020	14/09/2020	19/10/2020	13/10/2020	16/10/2020	21/10/2020	22/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
D46	09/10/2020	12/10/2020	16/11/2020	10/11/2020	13/11/2020	18/11/2020	19/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
D47	27/11/2020	30/11/2020	04/01/2021	22/12/2020	04/01/2021	06/01/2021	07/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
D48	23/12/2020	28/12/2020	01/02/2021	26/01/2021	29/01/2021	03/02/2021	04/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
D49	22/01/2021	25/01/2021	01/03/2021	23/02/2021	26/02/2021	03/03/2021	04/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
D50	19/02/2021	22/02/2021	29/03/2021	23/03/2021	26/03/2021	30/03/2021	31/03/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021

	Submission deadline (*)	Re-start date	CHMP Rapporteur AR (if PRAC is not involved)	Steps only applicable in case of PRAC involvement					Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
				CHMP Rapporteur AR	PRAC Rapporteur AR	Comments from PRAC (**)	Updated PRAC Rapporteur AR (***)	PRAC outcome			
D51	19/03/2021	22/03/2021	26/04/2021	20/04/2021	23/04/2021	28/04/2021	29/04/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
D52	23/04/2021	26/04/2021	31/05/2021	25/05/2021	28/05/2021	02/06/2021	03/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
D53	21/05/2021	24/05/2021	28/06/2021	22/06/2021	25/06/2021	30/06/2021	01/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
D54											
D55	16/07/2021	19/07/2021	23/08/2021	17/08/2021	20/08/2021	25/08/2021	26/08/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
D56	13/08/2021	16/08/2021	20/09/2021	14/09/2021	17/09/2021	22/09/2021	23/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
D57	10/09/2021	13/09/2021	18/10/2021	12/10/2021	15/10/2021	20/10/2021	21/10/2021	28/10/2021	29/10/2021	04/11/2021	11/11/2021
D58	15/10/2021	18/10/2021	22/11/2021	16/11/2021	19/11/2021	24/11/2021	25/11/2021	02/12/2021	06/12/2021	09/12/2021	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.

(**) 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.

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

	Submission deadline (*)	Re-start date	PRAC Rapporteur AR (~)	Comments from PRAC (**)(~)	Updated PRAC Rapporteur AR (***) (~)	CHMP Rapporteur AR	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
E1	24/01/2017	25/01/2017	30/01/2017	01/02/2017	02/02/2017	08/02/2017	09/02/2017	13/02/2017	16/02/2017	23/02/2017
E2	21/02/2017	22/02/2017	27/02/2017	01/03/2017	02/03/2017	08/03/2017	09/03/2017	13/03/2017	16/03/2017	23/03/2017
E3	22/03/2017	23/03/2017	27/03/2017	29/03/2017	30/03/2017	06/04/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
E4	18/04/2017	19/04/2017	24/04/2017	26/04/2017	27/04/2017	03/05/2017	05/05/2017	08/05/2017	11/05/2017	18/05/2017
E5	23/05/2017	24/05/2017	29/05/2017	31/05/2017	01/06/2017	07/06/2017	09/06/2017	12/06/2017	15/06/2017	22/06/2017
E6	20/06/2017	21/06/2017	26/06/2017	28/06/2017	29/06/2017	05/07/2017	06/07/2017	10/07/2017	13/07/2017	20/07/2017
E7										
E8	15/08/2017	16/08/2017	21/08/2017	23/08/2017	24/08/2017	30/08/2017	01/09/2017	04/09/2017	07/09/2017	14/09/2017
E9	12/09/2017	13/09/2017	18/09/2017	20/09/2017	21/09/2017	27/09/2017	28/09/2017	02/10/2017	05/10/2017	12/10/2017
E10	10/10/2017	11/10/2017	16/10/2017	18/10/2017	19/10/2017	25/10/2017	26/10/2017	30/10/2017	03/11/2017	09/11/2017
E11	14/11/2017	15/11/2017	20/11/2017	22/11/2017	23/11/2017	29/11/2017	30/11/2017	04/12/2017	07/12/2017	14/12/2017
E12	22/12/2017	27/12/2017	03/01/2018	04/01/2018	05/01/2018	10/01/2018	11/01/2018	15/01/2018	18/01/2018	25/01/2018
E13	23/01/2018	24/01/2018	29/01/2018	31/01/2018	01/02/2018	07/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
E14	20/02/2018	21/02/2018	26/02/2018	28/02/2018	01/03/2018	07/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
E15	27/03/2018	28/03/2018	03/04/2018	04/04/2018	05/04/2018	11/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
E16	30/04/2018	02/05/2018	04/05/2018	07/05/2018	08/05/2018	16/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
E17	29/05/2018	30/05/2018	04/06/2018	06/06/2018	07/06/2018	13/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
E18	26/06/2018	27/06/2018	02/07/2018	04/07/2018	05/07/2018	11/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
E19										
E20	21/08/2018	22/08/2018	28/08/2018	29/08/2018	30/08/2018	05/09/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
E21	18/09/2018	19/09/2018	24/09/2018	26/09/2018	27/09/2018	03/10/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
E22	16/10/2018	17/10/2018	22/10/2018	24/10/2018	25/10/2018	31/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
E23	13/11/2018	14/11/2018	19/11/2018	21/11/2018	22/11/2018	28/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
E24	21/12/2018	02/01/2019	07/01/2019	09/01/2019	10/01/2019	16/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019
E25	29/01/2019	30/01/2019	04/02/2019	06/02/2019	07/02/2019	13/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019

	Submission deadline (*)	Re-start date	PRAC Rapporteur AR (~)	Comments from PRAC (**)(~)	Updated PRAC Rapporteur AR (***) (~)	CHMP Rapporteur AR	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
E26	26/02/2019	27/02/2019	04/03/2019	06/03/2019	07/03/2019	13/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019
E27	27/03/2019	28/03/2019	01/04/2019	03/04/2019	04/04/2019	10/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
E28	29/04/2019	30/04/2019	06/05/2019	07/05/2019	08/05/2019	15/05/2019	16/05/2019	20/05/2019	23/05/2019	29/05/2019
E29	28/05/2019	29/05/2019	03/06/2019	05/06/2019	06/06/2019	12/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
E30	25/06/2019	26/06/2019	01/07/2019	03/07/2019	04/07/2019	10/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
E31										
E32	20/08/2019	21/08/2019	27/08/2019	28/08/2019	29/08/2019	04/09/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
E33	17/09/2019	18/09/2019	23/09/2019	25/09/2019	26/09/2019	02/10/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
E34	15/10/2019	16/10/2019	21/10/2019	23/10/2019	24/10/2019	30/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
E35	12/11/2019	13/11/2019	18/11/2019	20/11/2019	21/11/2019	27/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
E36	23/12/2019	01/01/2020	06/01/2020	08/01/2020	09/01/2020	15/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
E37	28/01/2020	29/01/2020	03/02/2020	05/02/2020	06/02/2020	12/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
E38	25/02/2020	26/02/2020	02/03/2020	04/03/2020	05/03/2020	11/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
E39	31/03/2020	01/04/2020	06/04/2020	07/04/2020	08/04/2020	15/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
E40	28/04/2020	29/04/2020	04/05/2020	06/05/2020	07/05/2020	13/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
E41	26/05/2020	27/05/2020	29/05/2020	03/06/2020	04/06/2020	10/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
E42	23/06/2020	24/06/2020	29/06/2020	01/07/2020	02/07/2020	08/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
E43										
E44	18/08/2020	19/08/2020	24/08/2020	26/08/2020	27/08/2020	02/09/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
E45	15/09/2020	16/09/2020	21/09/2020	23/09/2020	24/09/2020	30/09/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
E46	13/10/2020	14/10/2020	19/10/2020	21/10/2020	22/10/2020	28/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
E47	10/11/2020	11/11/2020	16/11/2020	18/11/2020	19/11/2020	25/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
E48	23/12/2020	30/12/2020	04/01/2021	06/01/2021	07/01/2021	13/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
E49	26/01/2021	27/01/2021	01/02/2021	03/02/2021	04/02/2021	10/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
E50	23/02/2021	24/02/2021	01/03/2021	03/03/2021	04/03/2021	10/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
E51	23/03/2021	24/03/2021	29/03/2021	30/03/2021	31/03/2021	07/04/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
E52	20/04/2021	21/04/2021	26/04/2021	28/04/2021	29/04/2021	05/05/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021

	Submission deadline (*)	Re-start date	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	CHMP Rapporteur AR	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
E53	25/05/2021	26/05/2021	31/05/2021	02/06/2021	03/06/2021	09/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
E54	22/06/2021	23/06/2021	28/06/2021	30/06/2021	01/07/2021	07/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
E55										
E56	17/08/2021	18/08/2021	23/08/2021	25/08/2021	26/08/2021	01/09/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
E57	14/09/2021	15/09/2021	20/09/2021	22/09/2021	23/09/2021	29/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
E58	12/10/2021	13/10/2021	18/10/2021	20/10/2021	21/10/2021	27/10/2021	28/10/2021	03/11/2021	05/11/2021	11/11/2021
E59	16/11/2021	17/11/2021	22/11/2021	24/11/2021	25/11/2021	01/12/2021	02/12/2021	06/12/2021	09/12/2021	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 partially falls under the remit of the PRAC (typically, when a RMP is 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

30-day immediate responses to RSI assessment timetable⁷

	Submission deadline (*)	Re-start date	CHMP Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Comments from CHMP (**)	Updated PRAC Rapporteur AR (***)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
F1	23/12/2016	04/01/2017	11/01/2017	11/01/2017	16/01/2017	16/01/2017	19/01/2017	19/01/2017	26/01/2017
F2	31/01/2017	01/02/2017	08/02/2017	08/02/2017	13/02/2017	13/02/2017	16/02/2017	16/02/2017	23/02/2017
F3	28/02/2017	01/03/2017	08/03/2017	08/03/2017	13/03/2017	13/03/2017	16/03/2017	16/03/2017	23/03/2017
F4	29/03/2017	30/03/2017	06/04/2017	06/04/2017	10/04/2017	10/04/2017	12/04/2017	12/04/2017	21/04/2017
F5	25/04/2017	26/04/2017	03/05/2017	03/05/2017	08/05/2017	08/05/2017	11/05/2017	11/05/2017	18/05/2017
F6	23/05/2017	31/05/2017	07/06/2017	07/06/2017	12/06/2017	12/06/2017	15/06/2017	15/06/2017	22/06/2017
F7	27/06/2017	28/06/2017	05/07/2017	05/07/2017	10/07/2017	10/07/2017	13/07/2017	13/07/2017	20/07/2017
F8									
F9									
F10	19/09/2017	20/09/2017	27/09/2017	27/09/2017	02/10/2017	02/10/2017	05/10/2017	05/10/2017	12/10/2017
F11	17/10/2017	18/10/2017	25/10/2017	25/10/2017	30/10/2017	30/10/2017	03/11/2017	03/11/2017	09/11/2017
F12	14/11/2017	22/11/2017	29/11/2017	29/11/2017	04/12/2017	04/12/2017	07/12/2017	07/12/2017	14/12/2017
F13	19/12/2017	03/01/2018	10/01/2018	10/01/2018	15/01/2018	15/01/2018	18/01/2018	18/01/2018	25/01/2018
F14	30/01/2018	31/01/2018	07/02/2018	07/02/2018	12/02/2018	12/02/2018	15/02/2018	15/02/2018	22/02/2018
F15	27/02/2018	28/02/2018	07/03/2018	07/03/2018	12/03/2018	12/03/2018	15/03/2018	15/03/2018	22/03/2018
F16	29/03/2018	30/03/2018	11/04/2018	11/04/2018	16/04/2018	16/04/2018	19/04/2018	19/04/2018	26/04/2018
F17	03/05/2018	04/05/2018	16/05/2018	16/05/2018	22/05/2018	22/05/2018	24/05/2018	24/05/2018	31/05/2018
F18	05/06/2018	06/06/2018	13/06/2018	13/06/2018	18/06/2018	18/06/2018	21/06/2018	21/06/2018	28/06/2018
F19	03/07/2018	04/07/2018	11/07/2018	11/07/2018	16/07/2018	16/07/2018	19/07/2018	19/07/2018	26/07/2018
F20									
F21									
F22	25/09/2018	26/09/2018	03/10/2018	03/10/2018	08/10/2018	08/10/2018	11/10/2018	11/10/2018	18/10/2018
F23	23/10/2018	24/10/2018	31/10/2018	31/10/2018	05/11/2018	05/11/2018	08/11/2018	08/11/2018	15/11/2018
F24	20/11/2018	21/11/2018	28/11/2018	28/11/2018	03/12/2018	03/12/2018	06/12/2018	06/12/2018	13/12/2018
F25	21/12/2018	02/01/2019	16/01/2019	16/01/2019	21/01/2019	21/01/2019	24/01/2019	24/01/2019	31/01/2019

	Submission deadline (*)	Re-start date	CHMP Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Comments from CHMP (**)	Updated PRAC Rapporteur AR (***)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
F26	05/02/2019	06/02/2019	13/02/2019	13/02/2019	18/02/2019	18/02/2019	21/02/2019	21/02/2019	28/02/2019
F27	05/03/2019	06/03/2019	13/03/2019	13/03/2019	18/03/2019	18/03/2019	21/03/2019	21/03/2019	28/03/2019
F28	03/04/2019	04/04/2019	10/04/2019	10/04/2019	15/04/2019	15/04/2019	17/04/2019	17/04/2019	26/04/2019
F29	02/05/2019	03/05/2019	15/05/2019	15/05/2019	20/05/2019	20/05/2019	23/05/2019	23/05/2019	29/05/2019
F30	04/06/2019	05/06/2019	12/06/2019	12/06/2019	17/06/2019	17/06/2019	20/06/2019	20/06/2019	27/06/2019
F31	02/07/2019	03/07/2019	10/07/2019	10/07/2019	15/07/2019	15/07/2019	18/07/2019	18/07/2019	25/07/2019
F32									
F33									
F34	24/09/2019	25/09/2019	02/10/2019	02/10/2019	07/10/2019	07/10/2019	10/10/2019	10/10/2019	17/10/2019
F35	22/10/2019	23/10/2019	30/10/2019	30/10/2019	04/11/2019	04/11/2019	07/11/2019	07/11/2019	14/11/2019
F36	19/11/2019	20/11/2019	27/11/2019	27/11/2019	02/12/2019	02/12/2019	05/12/2019	05/12/2019	12/12/2019
F37	23/12/2019	01/01/2020	15/01/2020	15/01/2020	20/01/2020	20/01/2020	23/01/2020	23/01/2020	30/01/2020
F38	04/02/2020	05/02/2020	12/02/2020	12/02/2020	17/02/2020	17/02/2020	20/02/2020	20/02/2020	27/02/2020
F39	03/03/2020	04/03/2020	11/03/2020	11/03/2020	16/03/2020	16/03/2020	19/03/2020	19/03/2020	26/03/2020
F40	02/04/2020	03/04/2020	15/04/2020	15/04/2020	20/04/2020	20/04/2020	23/04/2020	23/04/2020	30/04/2020
F41	05/05/2020	06/05/2020	13/05/2020	13/05/2020	18/05/2020	18/05/2020	20/05/2020	20/05/2020	28/05/2020
F42	02/06/2020	03/06/2020	10/06/2020	10/06/2020	15/06/2020	15/06/2020	18/06/2020	18/06/2020	25/06/2020
F43	30/06/2020	01/07/2020	08/07/2020	08/07/2020	13/07/2020	13/07/2020	16/07/2020	16/07/2020	23/07/2020
F44									
F45									
F46	22/09/2020	23/09/2020	30/09/2020	30/09/2020	05/10/2020	05/10/2020	08/10/2020	08/10/2020	15/10/2020
F47	20/10/2020	21/10/2020	28/10/2020	28/10/2020	03/11/2020	03/11/2020	05/11/2020	05/11/2020	12/11/2020
F48	17/11/2020	18/11/2020	25/11/2020	25/11/2020	30/11/2020	30/11/2020	03/12/2020	03/12/2020	10/12/2020
F49	23/12/2020	30/12/2020	13/01/2021	13/01/2021	18/01/2021	18/01/2021	21/01/2021	21/01/2021	28/01/2021
F50	02/02/2021	03/02/2021	10/02/2021	10/02/2021	15/02/2021	15/02/2021	18/02/2021	18/02/2021	25/02/2021
F51	02/03/2021	03/03/2021	10/03/2021	10/03/2021	15/03/2021	15/03/2021	18/03/2021	18/03/2021	25/03/2021
F52	30/03/2021	31/03/2021	07/04/2021	07/04/2021	12/04/2021	12/04/2021	15/04/2021	15/04/2021	22/04/2021

	Submission deadline (*)	Re-start date	CHMP Rapporteur AR	PRAC Rapporteur AR (~)	Comments from PRAC (**)(~)	Comments from CHMP (**)	Updated PRAC Rapporteur AR (***)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
F53	27/04/2021	28/04/2021	05/05/2021	05/05/2021	10/05/2021	10/05/2021	12/05/2021	12/05/2021	20/05/2021
F54	27/05/2021	28/05/2021	09/06/2021	09/06/2021	14/06/2021	14/06/2021	17/06/2021	17/06/2021	24/06/2021
F55	29/06/2021	30/06/2021	07/07/2021	07/07/2021	12/07/2021	12/07/2021	15/07/2021	15/07/2021	22/07/2021
F56									
F57									
F58	21/09/2021	22/09/2021	29/09/2021	29/09/2021	04/10/2021	04/10/2021	07/10/2021	07/10/2021	14/10/2021
F59	19/10/2021	20/10/2021	27/10/2021	27/10/2021	03/11/2021	03/11/2021	05/11/2021	05/11/2021	11/11/2021
F60	18/11/2021	19/11/2021	01/12/2021	01/12/2021	06/12/2021	06/12/2021	09/12/2021	09/12/2021	16/12/2021

(~) This timetable is only applicable when minor issues remain and, if applicable, 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 partially falls under the remit of the PRAC (typically, when a RMP is 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.