

9 February 2023
EMA/577385/2016 Rev.7
Human Medicines Division

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 and Co-Rapporteur assessment (**)(~)(****)	Updated PRAC Rapporteur AR (**)(~)	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (**)	Request for Supplementary Information (RSI) or Opinion
A1	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
A2	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
A3	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
A4	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
A5										
A6	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
A7	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
A8	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
A9	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
A10	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
A11	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
A12	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
A13	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
A14	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
A15	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
A16	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
A17										
A18	02/06/2021	19/06/2021	13/08/2021	20/08/2021	25/08/2021	26/08/2021	02/09/2021	06/09/2021	09/09/2021	16/09/2021
A19	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
A20	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
A21	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
A22	13/10/2021	30/10/2021	21/12/2021	03/01/2022	05/01/2022	06/01/2022	13/01/2022	17/01/2022	20/01/2022	27/01/2022
A23	10/11/2021	27/11/2021	21/01/2022	28/01/2022	02/02/2022	03/02/2022	10/02/2022	14/02/2022	17/02/2022	24/02/2022

	Submission deadline (*)	Start date (^)	CHMP (Co-) Rapporteur AR (****)	PRAC Rapporteur AR (~)	Comments from PRAC and Co-Rapporteur assessment (**)(~)(****)	Updated PRAC Rapporteur AR (***)(~)	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
A24	01/12/2021	25/12/2021	18/02/2022	25/02/2022	02/03/2022	03/03/2022	10/03/2022	14/03/2022	17/03/2022	24/03/2022
A25	06/01/2022	23/01/2022	18/03/2022	25/03/2022	30/03/2022	31/03/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
A26	02/02/2022	19/02/2022	13/04/2022	22/04/2022	26/04/2022	28/04/2022	05/05/2022	06/05/2022	12/05/2022	19/05/2022
A27	09/03/2022	26/03/2022	20/05/2022	25/05/2022	01/06/2022	02/06/2022	10/06/2022	13/06/2022	16/06/2022	23/06/2022
A28	06/04/2022	23/04/2022	17/06/2022	24/06/2022	29/06/2022	30/06/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
A29										
A30	01/06/2022	18/06/2022	12/08/2022	19/08/2022	24/08/2022	25/08/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
A31	29/06/2022	16/07/2022	09/09/2022	16/09/2022	21/09/2022	22/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
A32	27/07/2022	13/08/2022	07/10/2022	14/10/2022	19/10/2022	20/10/2022	27/10/2022	28/10/2022	03/11/2022	10/11/2022
A33	31/08/2022	17/09/2022	11/11/2022	18/11/2022	23/11/2022	24/11/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
A34	12/10/2022	29/10/2022	22/12/2022	03/01/2023	04/01/2023	05/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
A35	09/11/2022	26/11/2022	20/01/2023	27/01/2023	01/02/2023	02/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
A36	30/11/2022	31/12/2022	24/02/2023	03/03/2023	08/03/2023	09/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
A37	10/01/2023	27/01/2023	24/03/2023	31/03/2023	04/04/2023	05/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
A38	08/02/2023	25/02/2023	21/04/2023	28/04/2023	03/05/2023	04/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
A39	08/03/2023	25/03/2023	17/05/2023	26/05/2023	31/05/2023	01/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
A40	05/04/2023	22/04/2023	16/06/2023	23/06/2023	28/06/2023	29/06/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
A41										
A42	31/05/2023	17/06/2023	11/08/2023	18/08/2023	23/08/2023	24/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
A43	28/06/2023	15/07/2023	08/09/2023	15/09/2023	20/09/2023	21/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
A44	26/07/2023	12/08/2023	06/10/2023	13/10/2023	18/10/2023	19/10/2023	26/10/2023	30/10/2023	31/10/2023	09/11/2023
A45	30/08/2023	16/09/2023	10/11/2023	17/11/2023	22/11/2023	23/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
A46	11/10/2023	28/10/2023	21/12/2023	03/01/2024	04/01/2024	05/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
A47	08/11/2023	25/11/2023	19/01/2024	26/01/2024	31/01/2024	01/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
A48	29/11/2023	23/12/2023	16/02/2024	23/02/2024	28/02/2024	29/02/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024

	Submission deadline (*)	Start date (^)	CHMP (Co-) Rapporteur AR (****)	PRAC Rapporteur AR (~)	Comments from PRAC and Co-Rapporteur assessment (**) (~) (****)	Updated PRAC Rapporteur AR (***) (~)	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
A49	10/01/2024	27/01/2024	22/03/2024	27/03/2024	03/04/2024	04/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024
A50	14/02/2024	02/03/2024	26/04/2024	03/05/2024	07/05/2024	08/05/2024	16/05/2024	21/05/2024	23/05/2024	30/05/2024
A51	13/03/2024	30/03/2024	24/05/2024	31/05/2024	05/06/2024	06/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024
A52	10/04/2024	27/04/2024	21/06/2024	28/06/2024	03/07/2024	04/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024
A53										
A54	05/06/2024	22/06/2024	16/08/2024	23/08/2024	28/08/2024	29/08/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
A55	03/07/2024	20/07/2024	13/09/2024	20/09/2024	25/09/2024	26/09/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
A56	31/07/2024	17/08/2024	11/10/2024	18/10/2024	23/10/2024	24/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
A57	28/08/2024	14/09/2024	08/11/2024	15/11/2024	20/11/2024	21/11/2024	28/11/2024	02/12/2024	05/12/2024	12/12/2024

(→) 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.

(****) The CHMP Co-rapporteur introduces their assessment into the Rapporteur Day 80 Overview assessment report for non-COVID 19 related applications. The Rapporteur AR and Co-Rapporteur assessment will be both made available to the applicant

60-day initial submission assessment timetable¹

	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	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
B2	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
B3	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
B4	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
B5	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
B6											
B7	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
B8	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
B9	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
B10	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
B11	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
B12	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
B13	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
B14	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
B15	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
B16	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
B17	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
B18											
B19	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
B20	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
B21	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
B22	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
B23	12/11/2021	29/11/2021	03/01/2022	22/12/2021	03/01/2022	05/01/2022	06/01/2022	13/01/2022	17/01/2022	20/01/2022	27/01/2022
B24	26/11/2021	27/12/2021	31/01/2022	25/01/2022	28/01/2022	02/02/2022	03/02/2022	10/02/2022	14/02/2022	17/02/2022	24/02/2022

	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			
B25	07/01/2022	24/01/2022	28/02/2022	22/02/2022	25/02/2022	02/03/2022	03/03/2022	10/03/2022	14/03/2022	17/03/2022	24/03/2022
B26	02/02/2022	22/02/2022	28/03/2022	22/03/2022	25/03/2022	30/03/2022	31/03/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
B27	04/03/2022	21/03/2022	25/04/2022	19/04/2022	22/04/2022	26/04/2022	28/04/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
B28	08/04/2022	25/04/2022	30/05/2022	24/05/2022	30/05/2022	01/06/2022	02/06/2022	10/06/2022	13/06/2022	16/06/2022	23/06/2022
B29	06/05/2022	23/05/2022	27/06/2022	21/06/2022	24/06/2022	29/06/2022	30/06/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
B30											
B31	01/07/2022	18/07/2022	22/08/2022	16/08/2022	19/08/2022	24/08/2022	25/08/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
B32	29/07/2022	15/08/2022	19/09/2022	13/09/2022	16/09/2022	21/09/2022	22/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
B33	26/08/2022	12/09/2022	17/10/2022	11/10/2022	14/10/2022	19/10/2022	20/10/2022	27/10/2022	28/10/2022	03/11/2022	10/11/2022
B34	30/09/2022	17/10/2022	21/11/2022	15/11/2022	18/11/2022	23/11/2022	24/11/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
B35	11/11/2022	28/11/2022	03/01/2023	22/12/2022	03/01/2023	04/01/2023	05/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
B36	25/11/2022	26/12/2022	30/01/2023	24/01/2023	27/01/2023	01/02/2023	02/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
B37	13/01/2023	30/01/2023	06/03/2023	28/02/2023	03/03/2023	08/03/2023	09/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
B38	09/02/2023	26/02/2023	03/04/2023	28/03/2023	31/03/2023	04/04/2023	05/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
B39	10/03/2023	27/03/2023	02/05/2023	25/04/2023	28/04/2023	03/05/2023	04/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
B40	05/04/2023	24/04/2023	30/05/2023	23/05/2023	26/05/2023	31/05/2023	01/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
B41	05/05/2023	22/05/2023	26/06/2023	20/06/2023	23/06/2023	28/06/2023	29/06/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
B42											
B43	30/06/2023	17/07/2023	21/08/2023	14/08/2023	18/08/2023	23/08/2023	24/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
B44	28/07/2023	14/08/2023	18/09/2023	12/09/2023	15/09/2023	20/09/2023	21/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
B45	25/08/2023	11/09/2023	16/10/2023	10/10/2023	13/10/2023	18/10/2023	19/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
B46	29/09/2023	16/10/2023	20/11/2023	14/11/2023	17/11/2023	22/11/2023	23/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
B47	10/11/2023	27/11/2023	03/01/2024	21/12/2023	03/01/2024	04/01/2024	05/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
B48	24/11/2023	25/12/2023	29/01/2024	23/01/2024	26/01/2024	31/01/2024	01/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
B49	05/01/2024	22/01/2024	26/02/2024	20/02/2024	23/02/2024	28/02/2024	29/02/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024
B50	09/02/2024	26/02/2024	02/04/2024	25/03/2024	27/03/2024	03/04/2024	04/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024

	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			
B51	15/03/2024	01/04/2024	06/05/2024	30/04/2024	03/05/2024	07/05/2024	08/05/2024	16/05/2024	17/05/2024	23/05/2024	30/05/2024
B52	12/04/2024	29/04/2024	03/06/2024	28/05/2024	31/05/2024	05/06/2024	06/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024
B53	08/05/2024	27/05/2024	01/07/2024	25/06/2024	28/06/2024	03/07/2024	04/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024
B54											
B55	05/07/2024	22/07/2024	26/08/2024	20/08/2024	23/08/2024	28/08/2024	29/08/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
B56	02/08/2024	19/08/2024	23/09/2024	17/09/2024	20/09/2024	25/09/2024	26/09/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
B57	30/08/2024	16/09/2024	21/10/2024	15/10/2024	18/10/2024	23/10/2024	24/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
B58	27/09/2024	14/10/2024	18/11/2024	12/11/2024	15/11/2024	20/11/2024	21/11/2024	28/11/2024	02/12/2024	05/12/2024	12/12/2024

(-) 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	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
C2	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
C3	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
C4	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
C5	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
C6	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
C7										
C8	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
C9	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
C10	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
C11	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
C12	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
C13	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
C14	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
C15	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
C16	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
C17	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
C18	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
C19										
C20	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
C21	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
C22	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
C23	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
C24	26/11/2021	29/12/2021	03/01/2022	05/01/2022	06/01/2022	12/01/2022	13/01/2022	17/01/2022	20/01/2022	27/01/2022

	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
C25	14/01/2022	26/01/2022	31/01/2022	02/02/2022	03/02/2022	09/02/2022	10/02/2022	14/02/2022	17/02/2022	24/02/2022
C26	11/02/2022	23/02/2022	28/02/2022	02/03/2022	03/03/2022	09/03/2022	10/03/2022	14/03/2022	17/03/2022	24/03/2022
C27	11/03/2022	24/03/2022	28/03/2022	30/03/2022	31/03/2022	06/04/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
C28	08/04/2022	20/04/2022	25/04/2022	26/04/2022	28/04/2022	04/05/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
C29	13/05/2022	25/05/2022	30/05/2022	01/06/2022	02/06/2022	08/06/2022	10/06/2022	13/06/2022	16/06/2022	23/06/2022
C30	10/06/2022	22/06/2022	27/06/2022	29/06/2022	30/06/2022	06/07/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
C31										
C32	05/08/2022	17/08/2022	22/08/2022	24/08/2022	25/08/2022	31/08/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
C33	02/09/2022	14/09/2022	19/09/2022	21/09/2022	22/09/2022	28/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
C34	30/09/2022	12/10/2022	17/10/2022	19/10/2022	20/10/2022	26/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
C35	04/11/2022	16/11/2022	21/11/2022	23/11/2022	24/11/2022	30/11/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
C36	25/11/2022	28/12/2022	03/01/2023	04/01/2023	05/01/2023	11/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
C37	13/01/2023	25/01/2023	30/01/2023	01/02/2023	02/02/2023	08/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
C38	17/02/2023	01/03/2023	06/03/2023	08/03/2023	09/03/2023	15/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
C39	17/03/2023	28/03/2023	03/04/2023	04/04/2023	05/04/2023	12/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
C40	14/04/2023	26/04/2023	02/05/2023	03/05/2023	04/05/2023	10/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
C41	12/05/2023	24/05/2023	30/05/2023	31/05/2023	01/06/2023	07/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
C42	09/06/2023	21/06/2023	26/06/2023	28/06/2023	29/06/2023	05/07/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
C43										
C44	04/08/2023	16/08/2023	21/08/2023	23/08/2023	24/08/2023	30/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
C45	01/09/2023	13/09/2023	18/09/2023	20/09/2023	21/09/2023	27/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
C46	29/09/2023	11/10/2023	16/10/2023	18/10/2023	19/10/2023	25/10/2023	26/10/2023	30/10/2023	31/10/2023	09/11/2023
C47	03/11/2023	15/11/2023	20/11/2023	22/11/2023	23/11/2023	29/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
C48	24/11/2023	27/12/2023	03/01/2024	04/01/2024	05/01/2024	10/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
C49	12/01/2024	24/01/2024	29/01/2024	31/01/2024	01/02/2024	07/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
C50	09/02/2024	21/02/2024	26/02/2024	28/02/2024	29/02/2024	06/03/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024

	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
C51	15/03/2024	27/03/2024	02/04/2024	03/04/2024	04/04/2024	10/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024
C52	19/04/2024	01/05/2024	06/05/2024	07/05/2024	08/05/2024	15/05/2024	16/05/2024	21/05/2024	23/05/2024	30/05/2024
C53	17/05/2024	29/05/2024	03/06/2024	05/06/2024	06/06/2024	12/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024
C54	14/06/2024	26/06/2024	01/07/2024	03/07/2024	04/07/2024	10/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024
C55										
C56	09/08/2024	21/08/2024	26/08/2024	28/08/2024	29/08/2024	04/09/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
C57	06/09/2024	18/09/2024	23/09/2024	25/09/2024	26/09/2024	02/10/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
C58	04/10/2024	16/10/2024	21/10/2024	23/10/2024	24/10/2024	30/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
C59	31/10/2024	13/11/2024	18/11/2024	20/11/2024	21/11/2024	27/11/2024	28/11/2024	02/12/2024	05/12/2024	12/12/2024

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

(*) The 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	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
D2	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
D3	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
D4	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
D5	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
D6											
D7	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
D8	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
D9	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
D10	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
D11	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
D12	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
D13	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
D14	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
D15	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
D16	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
D17	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
D18											
D19	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
D20	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
D21	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
D22	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
D23	26/11/2021	29/11/2021	03/01/2022	22/12/2021	03/01/2022	05/01/2022	06/01/2022	13/01/2022	17/01/2022	20/01/2022	27/01/2022
D24	22/12/2021	27/12/2021	31/01/2022	25/01/2022	28/01/2022	02/02/2022	03/02/2022	10/02/2022	14/02/2022	17/02/2022	24/02/2022

	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	21/01/2022	24/01/2022	28/02/2022	22/02/2022	25/02/2022	02/03/2022	03/03/2022	10/03/2022	14/03/2022	17/03/2022	24/03/2022
D26	18/02/2022	22/02/2022	28/03/2022	22/03/2022	25/03/2022	30/03/2022	31/03/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
D27	18/03/2022	21/03/2022	25/04/2022	19/04/2022	22/04/2022	26/04/2022	28/04/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
D28	22/04/2022	25/04/2022	30/05/2022	24/05/2022	30/05/2022	01/06/2022	02/06/2022	10/06/2022	13/06/2022	16/06/2022	23/06/2022
D29	20/05/2022	23/05/2022	27/06/2022	21/06/2022	24/06/2022	29/06/2022	30/06/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
D30											
D31	15/07/2022	18/07/2022	22/08/2022	16/08/2022	19/08/2022	24/08/2022	25/08/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
D32	12/08/2022	15/08/2022	19/09/2022	13/09/2022	16/09/2022	21/09/2022	22/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
D33	09/09/2022	12/09/2022	17/10/2022	11/10/2022	14/10/2022	19/10/2022	20/10/2022	27/10/2022	28/10/2022	03/11/2022	10/11/2022
D34	14/10/2022	17/10/2022	21/11/2022	15/11/2022	18/11/2022	23/11/2022	24/11/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
D35	25/11/2022	28/11/2022	03/01/2023	22/12/2022	03/01/2023	04/01/2023	05/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
D36	22/12/2022	26/12/2022	30/01/2023	24/01/2023	27/01/2023	01/02/2023	02/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
D37	27/01/2023	30/01/2023	06/03/2023	28/02/2023	03/03/2023	08/03/2023	09/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
D38	23/02/2023	26/02/2023	03/04/2023	28/03/2023	31/03/2023	04/04/2023	05/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
D39	24/03/2023	27/03/2023	02/05/2023	25/04/2023	28/04/2023	03/05/2023	04/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
D40	21/04/2023	24/04/2023	30/05/2023	23/05/2023	26/05/2023	31/05/2023	01/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
D41	17/05/2023	22/05/2023	26/06/2023	20/06/2023	23/06/2023	28/06/2023	29/06/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
D42											
D43	14/07/2023	17/07/2023	21/08/2023	14/08/2023	18/08/2023	23/08/2023	24/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
D44	11/08/2023	14/08/2023	18/09/2023	12/09/2023	15/09/2023	20/09/2023	21/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
D45	08/09/2023	11/09/2023	16/10/2023	10/10/2023	13/10/2023	18/10/2023	19/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
D46	13/10/2023	16/10/2023	20/11/2023	14/11/2023	17/11/2023	22/11/2023	23/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
D47	24/11/2023	27/11/2023	03/01/2024	21/12/2023	03/01/2024	04/01/2024	05/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
D48	21/12/2023	25/12/2023	29/01/2024	23/01/2024	26/01/2024	31/01/2024	01/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
D49	19/01/2024	22/01/2024	26/02/2024	20/02/2024	23/02/2024	28/02/2024	29/02/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024
D50	23/02/2024	26/02/2024	02/04/2024	25/03/2024	27/03/2024	03/04/2024	04/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024

	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	27/03/2024	01/04/2024	06/05/2024	30/04/2024	03/05/2024	07/05/2024	08/05/2024	16/05/2024	17/05/2024	23/05/2024	30/05/2024
D52	26/04/2024	29/04/2024	03/06/2024	28/05/2024	31/05/2024	05/06/2024	06/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024
D53	24/05/2024	27/05/2024	01/07/2024	25/06/2024	28/06/2024	03/07/2024	04/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024
D54											
D55	19/07/2024	22/07/2024	26/08/2024	20/08/2024	23/08/2024	28/08/2024	29/08/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
D56	16/08/2024	19/08/2024	23/09/2024	17/09/2024	20/09/2024	25/09/2024	26/09/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
D57	13/09/2024	16/09/2024	21/10/2024	15/10/2024	18/10/2024	23/10/2024	24/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
D58	11/10/2024	14/10/2024	18/11/2024	12/11/2024	15/11/2024	20/11/2024	21/11/2024	28/11/2024	02/12/2024	05/12/2024	12/12/2024

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

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

(**) 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	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
E2	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
E3	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
E4	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
E5	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
E6	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
E7										
E8	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
E9	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
E10	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
E11	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
E12	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
E13	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
E14	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
E15	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
E16	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
E17	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
E18	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
E19										
E20	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
E21	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
E22	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
E23	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
E24	22/12/2021	29/12/2021	03/01/2022	05/01/2022	06/01/2022	12/01/2022	13/01/2022	17/01/2022	20/01/2022	27/01/2022
E25	25/01/2022	26/01/2022	31/01/2022	02/02/2022	03/02/2022	09/02/2022	10/02/2022	14/02/2022	17/02/2022	24/02/2022

	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	22/02/2022	23/02/2022	28/02/2022	02/03/2022	03/03/2022	09/03/2022	10/03/2022	14/03/2022	17/03/2022	24/03/2022
E27	23/03/2022	24/03/2022	28/03/2022	30/03/2022	31/03/2022	06/04/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
E28	19/04/2022	20/04/2022	25/04/2022	26/04/2022	28/04/2022	04/05/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
E29	24/05/2022	25/05/2022	30/05/2022	01/06/2022	02/06/2022	08/06/2022	10/06/2022	13/06/2022	16/06/2022	23/06/2022
E30	21/06/2022	22/06/2022	27/06/2022	29/06/2022	30/06/2022	06/07/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
E31										
E32	16/08/2022	17/08/2022	22/08/2022	24/08/2022	25/08/2022	31/08/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
E33	13/09/2022	14/09/2022	19/09/2022	21/09/2022	22/09/2022	28/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
E34	11/10/2022	12/10/2022	17/10/2022	19/10/2022	20/10/2022	26/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
E35	15/11/2022	16/11/2022	21/11/2022	23/11/2022	24/11/2022	30/11/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
E36	22/12/2022	28/12/2022	03/01/2023	04/01/2023	05/01/2023	11/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
E37	24/01/2023	25/01/2023	30/01/2023	01/02/2023	02/02/2023	08/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
E38	28/02/2023	01/03/2023	06/03/2023	08/03/2023	09/03/2023	15/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
E39	27/03/2023	28/03/2023	03/04/2023	04/04/2023	05/04/2023	12/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
E40	25/04/2023	26/04/2023	02/05/2023	03/05/2023	04/05/2023	10/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
E41	23/05/2023	24/05/2023	30/05/2023	31/05/2023	01/06/2023	07/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
E42	20/06/2023	21/06/2023	26/06/2023	28/06/2023	29/06/2023	05/07/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
E43										
E44	14/08/2023	16/08/2023	21/08/2023	23/08/2023	24/08/2023	30/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
E45	12/09/2023	13/09/2023	18/09/2023	20/09/2023	21/09/2023	27/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
E46	10/10/2023	11/10/2023	16/10/2023	18/10/2023	19/10/2023	25/10/2023	26/10/2023	30/10/2023	31/10/2023	09/11/2023
E47	14/11/2023	15/11/2023	20/11/2023	22/11/2023	23/11/2023	29/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
E48	21/12/2023	27/12/2023	03/01/2024	04/01/2024	05/01/2024	10/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
E49	23/01/2024	24/01/2024	29/01/2024	31/01/2024	01/02/2024	07/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
E50	20/02/2024	21/02/2024	26/02/2024	28/02/2024	29/02/2024	06/03/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024
E51	26/03/2024	27/03/2024	02/04/2024	03/04/2024	04/04/2024	10/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024
E52	30/04/2024	01/05/2024	06/05/2024	07/05/2024	08/05/2024	15/05/2024	16/05/2024	21/05/2024	23/05/2024	30/05/2024

	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	28/05/2024	29/05/2024	03/06/2024	05/06/2024	06/06/2024	12/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024
E54	25/06/2024	26/06/2024	01/07/2024	03/07/2024	04/07/2024	10/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024
E55										
E56	20/08/2024	21/08/2024	26/08/2024	28/08/2024	29/08/2024	04/09/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
E57	17/09/2024	18/09/2024	23/09/2024	25/09/2024	26/09/2024	02/10/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
E58	15/10/2024	16/10/2024	21/10/2024	23/10/2024	24/10/2024	30/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
E59	12/11/2024	13/11/2024	18/11/2024	20/11/2024	21/11/2024	27/11/2024	28/11/2024	02/12/2024	05/12/2024	12/12/2024

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

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

(~) Step applicable only if the submission 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	23/12/2019	01/01/2020	15/01/2020	15/01/2020	20/01/2020	20/01/2020	23/01/2020	23/01/2020	30/01/2020
F2	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
F3	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
F4	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
F5	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
F6	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
F7	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
F8									
F9	25/08/2020	26/08/2020	02/09/2020	02/09/2020	07/09/2020	07/09/2020	10/09/2020	10/09/2020	17/09/2020
F10	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
F11	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
F12	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
F13	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
F14	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
F15	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
F16	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
F17	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
F18	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
F19	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
F20									
F21	24/08/2021	25/08/2021	01/09/2021	01/09/2021	06/09/2021	06/09/2021	09/09/2021	09/09/2021	16/09/2021
F22	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
F23	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
F24	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
F25	22/12/2021	29/12/2021	12/01/2022	12/01/2022	17/01/2022	17/01/2022	20/01/2022	20/01/2022	27/01/2022

	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	01/02/2022	02/02/2022	09/02/2022	09/02/2022	14/02/2022	14/02/2022	17/02/2022	17/02/2022	24/02/2022
F27	01/03/2022	02/03/2022	09/03/2022	09/03/2022	14/03/2022	14/03/2022	17/03/2022	17/03/2022	24/03/2022
F28	30/03/2022	31/03/2022	06/04/2022	06/04/2022	11/04/2022	11/04/2022	13/04/2022	13/04/2022	22/04/2022
F29	26/04/2022	27/04/2022	04/05/2022	04/05/2022	10/05/2022	10/05/2022	12/05/2022	12/05/2022	19/05/2022
F30	25/05/2022	27/05/2022	08/06/2022	08/06/2022	13/06/2022	13/06/2022	16/06/2022	16/06/2022	23/06/2022
F31	28/06/2022	29/06/2022	06/07/2022	06/07/2022	11/07/2022	11/07/2022	14/07/2022	14/07/2022	21/07/2022
F32									
F33	16/08/2022	17/08/2022	31/08/2022	31/08/2022	05/09/2022	05/09/2022	08/09/2022	08/09/2022	15/09/2022
F34	20/09/2022	21/09/2022	28/09/2022	28/09/2022	03/10/2022	03/10/2022	06/10/2022	06/10/2022	13/10/2022
F35	18/10/2022	19/10/2022	26/10/2022	26/10/2022	28/10/2022	28/10/2022	03/11/2022	03/11/2022	10/11/2022
F36	16/11/2022	18/11/2022	30/11/2022	30/11/2022	05/12/2022	05/12/2022	08/12/2022	08/12/2022	15/12/2022
F37	22/12/2022	28/12/2022	11/01/2023	11/01/2023	16/01/2023	16/01/2023	19/01/2023	19/01/2023	26/01/2023
F38	31/01/2023	01/02/2023	08/02/2023	08/02/2023	13/02/2023	13/02/2023	16/02/2023	16/02/2023	23/02/2023
F39	28/02/2023	01/03/2023	15/03/2023	15/03/2023	20/03/2023	20/03/2023	23/03/2023	23/03/2023	30/03/2023
F40	03/04/2023	04/04/2023	12/04/2023	12/04/2023	17/04/2023	17/04/2023	20/04/2023	20/04/2023	26/04/2023
F41	02/05/2023	03/05/2023	10/05/2023	10/05/2023	15/05/2023	15/05/2023	17/05/2023	17/05/2023	25/05/2023
F42	30/05/2023	31/05/2023	07/06/2023	07/06/2023	12/06/2023	12/06/2023	15/06/2023	15/06/2023	22/06/2023
F43	27/06/2023	28/06/2023	05/07/2023	05/07/2023	10/07/2023	10/07/2023	13/07/2023	13/07/2023	20/07/2023
F44									
F45	14/08/2023	16/08/2023	30/08/2023	30/08/2023	04/09/2023	04/09/2023	07/09/2023	07/09/2023	14/09/2023
F46	19/09/2023	20/09/2023	27/09/2023	27/09/2023	02/10/2023	02/10/2023	05/10/2023	05/10/2023	12/10/2023
F47	17/10/2023	18/10/2023	25/10/2023	25/10/2023	30/10/2023	30/10/2023	31/10/2023	31/10/2023	09/11/2023
F48	16/11/2023	17/11/2023	29/11/2023	29/11/2023	04/12/2023	04/12/2023	07/12/2023	07/12/2023	14/12/2023
F49	21/12/2023	27/12/2023	10/01/2024	10/01/2024	15/01/2024	15/01/2024	18/01/2024	18/01/2024	25/01/2024
F50	30/01/2024	31/01/2024	07/02/2024	07/02/2024	12/02/2024	12/02/2024	15/02/2024	15/02/2024	22/02/2024
F51	27/02/2024	28/02/2024	06/03/2024	06/03/2024	11/03/2024	11/03/2024	14/03/2024	14/03/2024	21/03/2024
F52	27/03/2024	29/03/2024	10/04/2024	10/04/2024	15/04/2024	15/04/2024	18/04/2024	18/04/2024	25/04/2024

	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	02/05/2024	03/05/2024	15/05/2024	15/05/2024	21/05/2024	21/05/2024	23/05/2024	23/05/2024	30/05/2024
F54	04/06/2024	05/06/2024	12/06/2024	12/06/2024	17/06/2024	17/06/2024	20/06/2024	20/06/2024	27/06/2024
F55	02/07/2024	03/07/2024	10/07/2024	10/07/2024	15/07/2024	15/07/2024	18/07/2024	18/07/2024	25/07/2024
F56									
F57	20/08/2024	21/08/2024	04/09/2024	04/09/2024	09/09/2024	09/09/2024	12/09/2024	12/09/2024	19/09/2024
F58	24/09/2024	25/09/2024	02/10/2024	02/10/2024	07/10/2024	07/10/2024	10/10/2024	10/10/2024	17/10/2024
F59	22/10/2024	23/10/2024	30/10/2024	30/10/2024	04/11/2024	04/11/2024	07/11/2024	07/11/2024	14/11/2024
F60	19/11/2024	20/11/2024	27/11/2024	27/11/2024	02/12/2024	02/12/2024	05/12/2024	05/12/2024	12/12/2024

(-) 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.