



18 January 2019
EMA/577387/2016 Rev.3
Human Medicines Evaluation

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

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

Initial submission assessment timetable

[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](#)

* alternative monthly timetables have an outcome during the week of the PRAC meeting (CHMP adoption via written procedure)

60-day initial assessment timetable⁷

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

	Submission deadline (*)	Start date (^)	CHMP Rapporteur AR (~)	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CHMP (**)	Updated PRAC Rapporteur AR (***)	Updated CHMP Rapporteur AR (***) (~)	PRAC outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
A25	25/01/2019	12/02/2019	18/03/2019	25/03/2019	29/03/2019	01/04/2019	02/04/2019	04/04/2019	09/04/2019	09/04/2019	11/04/2019
A26	01/03/2019	19/03/2019	23/04/2019	29/04/2019	03/05/2019	06/05/2019	07/05/2019	08/05/2019	14/05/2019	14/05/2019	16/05/2019
A27	29/03/2019	17/04/2019	20/05/2019	27/05/2019	03/06/2019	03/06/2019	05/06/2019	06/06/2019	12/06/2019	12/06/2019	14/06/2019
A28	26/04/2019	14/05/2019	17/06/2019	24/06/2019	28/06/2019	01/07/2019	02/07/2019	04/07/2019	09/07/2019	09/07/2019	11/07/2019
A29											
A30	21/06/2019	09/07/2019	12/08/2019	19/08/2019	23/08/2019	27/08/2019	27/08/2019	29/08/2019	03/09/2019	03/09/2019	05/09/2019
A31	19/07/2019	06/08/2019	09/09/2019	16/09/2019	20/09/2019	23/09/2019	24/09/2019	26/09/2019	01/10/2019	01/10/2019	03/10/2019
A32	16/08/2019	03/09/2019	07/10/2019	14/10/2019	18/10/2019	21/10/2019	22/10/2019	24/10/2019	29/10/2019	29/10/2019	31/10/2019
A33	13/09/2019	01/10/2019	04/11/2019	11/11/2019	15/11/2019	18/11/2019	19/11/2019	21/11/2019	26/11/2019	26/11/2019	28/11/2019
A34	31/10/2019	19/11/2019	19/12/2019	03/01/2020	07/01/2020	07/01/2020	09/01/2020	09/01/2020	14/01/2020	14/01/2020	16/01/2020
A35	29/11/2019	17/12/2019	20/01/2020	27/01/2020	31/01/2020	03/02/2020	04/02/2020	06/02/2020	11/02/2020	11/02/2020	13/02/2020
A36	20/12/2019	14/01/2020	17/02/2020	24/02/2020	28/02/2020	02/03/2020	03/03/2020	05/03/2020	10/03/2020	10/03/2020	12/03/2020
A37	31/01/2020	19/02/2020	23/03/2020	30/03/2020	03/04/2020	06/04/2020	07/04/2020	08/04/2020	15/04/2020	15/04/2020	17/04/2020
A38	28/02/2020	17/03/2020	20/04/2020	27/04/2020	04/05/2020	04/05/2020	06/05/2020	07/05/2020	12/05/2020	12/05/2020	14/05/2020
A39	27/03/2020	14/04/2020	18/05/2020	25/05/2020	29/05/2020	02/06/2020	02/06/2020	04/06/2020	09/06/2020	09/06/2020	11/06/2020
A40	24/04/2020	12/05/2020	15/06/2020	22/06/2020	26/06/2020	29/06/2020	30/06/2020	02/07/2020	07/07/2020	07/07/2020	09/07/2020
A41											
A42	19/06/2020	08/07/2020	10/08/2020	17/08/2020	21/08/2020	24/08/2020	25/08/2020	27/08/2020	02/09/2020	02/09/2020	04/09/2020
A43	17/07/2020	04/08/2020	07/09/2020	14/09/2020	18/09/2020	21/09/2020	22/09/2020	24/09/2020	29/09/2020	29/09/2020	01/10/2020
A44	14/08/2020	01/09/2020	05/10/2020	12/10/2020	16/10/2020	19/10/2020	20/10/2020	22/10/2020	27/10/2020	27/10/2020	29/10/2020
A45	11/09/2020	29/09/2020	03/11/2020	09/11/2020	13/11/2020	16/11/2020	17/11/2020	19/11/2020	24/11/2020	24/11/2020	26/11/2020
A46	30/10/2020	17/11/2020	18/12/2020	21/12/2020	05/01/2021	06/01/2021	07/01/2021	07/01/2021	12/01/2021	12/01/2021	14/01/2021
A47	27/11/2020	15/12/2020	18/01/2021	25/01/2021	29/01/2021	01/02/2021	02/02/2021	04/02/2021	09/02/2021	09/02/2021	11/02/2021
A48	22/12/2020	12/01/2021	15/02/2021	22/02/2021	26/02/2021	01/03/2021	02/03/2021	04/03/2021	09/03/2021	09/03/2021	11/03/2021
A49	22/01/2021	10/02/2021	15/03/2021	22/03/2021	26/03/2021	29/03/2021	30/03/2021	31/03/2021	07/04/2021	07/04/2021	09/04/2021
A50	19/02/2021	09/03/2021	12/04/2021	19/04/2021	23/04/2021	26/04/2021	27/04/2021	29/04/2021	04/05/2021	04/05/2021	06/05/2021

	Submission deadline (*)	Start date (^)	CHMP Rapporteur AR (~)	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CHMP (**)	Updated PRAC Rapporteur AR (***)	Updated CHMP Rapporteur AR (***) (~)	PRAC outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
A51	26/03/2021	13/04/2021	17/05/2021	25/05/2021	28/05/2021	31/05/2021	01/06/2021	03/06/2021	08/06/2021	08/06/2021	10/06/2021
A52	23/04/2021	11/05/2021	14/06/2021	21/06/2021	25/06/2021	28/06/2021	29/06/2021	01/07/2021	06/07/2021	06/07/2021	08/07/2021
A53											
A54	18/06/2021	07/07/2021	09/08/2021	16/08/2021	20/08/2021	23/08/2021	24/08/2021	26/08/2021	01/09/2021	01/09/2021	03/09/2021
A55	16/07/2021	03/08/2021	06/09/2021	13/09/2021	17/09/2021	20/09/2021	21/09/2021	23/09/2021	28/09/2021	28/09/2021	30/09/2021
A56	13/08/2021	31/08/2021	04/10/2021	11/10/2021	15/10/2021	18/10/2021	19/10/2021	21/10/2021	26/10/2021	26/10/2021	28/10/2021
A57	17/09/2021	05/10/2021	08/11/2021	15/11/2021	19/11/2021	22/11/2021	23/11/2021	25/11/2021	30/11/2021	30/11/2021	02/12/2021

(~) This timetable applies to variations involving the PRAC (either CHMP-led with PRAC involvement or PRAC-led). It is the default timetable for the assessment of PRAC-involving variations which do not lead to an immediate EC Decision after Opinion (mainly variations for addition of/changes to indications, for new contraindications, for changes in posology or variations with a DHPC) and which are not expected to require a discussion during the CHMP plenary meeting. The Agency will advise whether an immediate EC Decision or a CHMP discussion is required.

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

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

(~) Step not applicable in case of PRAC-led variation (i.e. one including only an RMP update and/or results of a non-interventional PASS without consequence to the SmPC and PL).

(**) 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.

(#) Adoption of the outcome (Opinion or RSI) via written procedure is necessary when the adoption occurs outside of the CHMP plenary meeting.

30-day initial assessment timetable⁷

	Submission deadline (*)	Start date (^)	CHMP Rapporteur AR (~)	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CHMP (**)	Updated PRAC Rapporteur AR (***)	Updated CHMP Rapporteur AR (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
B1	27/01/2017	09/02/2017	22/02/2017	24/02/2017	27/02/2017	27/02/2017	28/02/2017	02/03/2017	07/03/2017	07/03/2017	09/03/2017
B2	24/02/2017	09/03/2017	22/03/2017	24/03/2017	27/03/2017	27/03/2017	28/03/2017	30/03/2017	04/04/2017	04/04/2017	06/04/2017
B3	25/03/2017	07/04/2017	20/04/2017	21/04/2017	25/04/2017	25/04/2017	26/04/2017	28/04/2017	03/05/2017	03/05/2017	05/05/2017
B4	29/04/2017	12/05/2017	22/05/2017	24/05/2017	30/05/2017	30/05/2017	31/05/2017	02/06/2017	07/06/2017	07/06/2017	09/06/2017
B5	24/05/2017	08/06/2017	21/06/2017	23/06/2017	26/06/2017	26/06/2017	27/06/2017	29/06/2017	04/07/2017	04/07/2017	06/07/2017
B6											
B7	22/07/2017	04/08/2017	17/08/2017	18/08/2017	22/08/2017	22/08/2017	23/08/2017	25/08/2017	30/08/2017	30/08/2017	01/09/2017
B8	18/08/2017	31/08/2017	13/09/2017	15/09/2017	18/09/2017	18/09/2017	19/09/2017	21/09/2017	26/09/2017	26/09/2017	28/09/2017
B9	15/09/2017	28/09/2017	11/10/2017	13/10/2017	16/10/2017	16/10/2017	17/10/2017	19/10/2017	24/10/2017	24/10/2017	26/10/2017
B10	20/10/2017	02/11/2017	15/11/2017	17/11/2017	20/11/2017	20/11/2017	21/11/2017	23/11/2017	28/11/2017	28/11/2017	30/11/2017
B11	02/12/2017	15/12/2017	21/12/2017	03/01/2018	04/01/2018	04/01/2018	05/01/2018	05/01/2018	09/01/2018	09/01/2018	11/01/2018
B12	21/12/2017	11/01/2018	24/01/2018	26/01/2018	29/01/2018	29/01/2018	30/01/2018	01/02/2018	06/02/2018	06/02/2018	08/02/2018
B13	26/01/2018	08/02/2018	21/02/2018	23/02/2018	26/02/2018	26/02/2018	27/02/2018	01/03/2018	06/03/2018	06/03/2018	08/03/2018
B14	02/03/2018	15/03/2018	28/03/2018	03/04/2018	04/04/2018	04/04/2018	05/04/2018	05/04/2018	10/04/2018	10/04/2018	12/04/2018
B15	07/04/2018	20/04/2018	30/04/2018	03/05/2018	07/05/2018	07/05/2018	08/05/2018	08/05/2018	15/05/2018	15/05/2018	17/05/2018
B16	04/05/2018	17/05/2018	30/05/2018	01/06/2018	04/06/2018	04/06/2018	05/06/2018	07/06/2018	12/06/2018	12/06/2018	14/06/2018
B17	01/06/2018	14/06/2018	27/06/2018	29/06/2018	02/07/2018	02/07/2018	03/07/2018	05/07/2018	10/07/2018	10/07/2018	12/07/2018
B18											
B19	27/07/2018	09/08/2018	22/08/2018	24/08/2018	28/08/2018	28/08/2018	29/08/2018	30/08/2018	04/09/2018	04/09/2018	06/09/2018
B20	24/08/2018	06/09/2018	19/09/2018	21/09/2018	24/09/2018	24/09/2018	25/09/2018	27/09/2018	02/10/2018	02/10/2018	04/10/2018
B21	20/09/2018	03/10/2018	16/10/2018	18/10/2018	22/10/2018	22/10/2018	24/10/2018	25/10/2018	29/10/2018	29/10/2018	31/10/2018
B22	19/10/2018	01/11/2018	14/11/2018	16/11/2018	19/11/2018	19/11/2018	20/11/2018	22/11/2018	27/11/2018	27/11/2018	29/11/2018
B23	30/11/2018	20/12/2018	03/01/2019	07/01/2019	09/01/2019	09/01/2019	10/01/2019	10/01/2019	15/01/2019	15/01/2019	17/01/2019
B24	04/01/2019	17/01/2019	30/01/2019	01/02/2019	04/02/2019	04/02/2019	05/02/2019	07/02/2019	12/02/2019	12/02/2019	14/02/2019

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B25	01/02/2019	14/02/2019	27/02/2019	01/03/2019	04/03/2019	04/03/2019	05/03/2019	07/03/2019	12/03/2019	12/03/2019	14/03/2019
B26	01/03/2019	14/03/2019	27/03/2019	29/03/2019	01/04/2019	01/04/2019	02/04/2019	04/04/2019	09/04/2019	09/04/2019	11/04/2019
B27	05/04/2019	18/04/2019	30/04/2019	03/05/2019	06/05/2019	06/05/2019	07/05/2019	08/05/2019	14/05/2019	14/05/2019	16/05/2019
B28	03/05/2019	17/05/2019	29/05/2019	29/05/2019	03/06/2019	03/06/2019	04/06/2019	06/06/2019	12/06/2019	12/06/2019	14/06/2019
B29	29/05/2019	13/06/2019	26/06/2019	28/06/2019	01/07/2019	01/07/2019	02/07/2019	04/07/2019	09/07/2019	09/07/2019	11/07/2019
B30											
B31	26/07/2019	08/08/2019	21/08/2019	23/08/2019	27/08/2019	27/08/2019	28/08/2019	29/08/2019	03/09/2019	03/09/2019	05/09/2019
B32	23/08/2019	05/09/2019	18/09/2019	20/09/2019	23/09/2019	23/09/2019	24/09/2019	26/09/2019	01/10/2019	01/10/2019	03/10/2019
B33	20/09/2019	03/10/2019	16/10/2019	18/10/2019	21/10/2019	21/10/2019	22/10/2019	24/10/2019	29/10/2019	29/10/2019	31/10/2019
B34	18/10/2019	31/10/2019	13/11/2019	15/11/2019	18/11/2019	18/11/2019	19/11/2019	21/11/2019	26/11/2019	26/11/2019	28/11/2019
B35	29/11/2019	19/12/2019	03/01/2020	07/01/2020	09/01/2020	09/01/2020	10/01/2020	10/01/2020	14/01/2020	14/01/2020	16/01/2020
B36	03/01/2020	16/01/2020	29/01/2020	31/01/2020	03/02/2020	03/02/2020	04/02/2020	06/02/2020	11/02/2020	11/02/2020	13/02/2020
B37	31/01/2020	13/02/2020	26/02/2020	28/02/2020	02/03/2020	02/03/2020	03/03/2020	05/03/2020	10/03/2020	10/03/2020	12/03/2020
B38	06/03/2020	20/03/2020	01/04/2020	03/04/2020	06/04/2020	06/04/2020	07/04/2020	08/04/2020	15/04/2020	15/04/2020	17/04/2020
B39	03/04/2020	16/04/2020	29/04/2020	30/04/2020	04/05/2020	04/05/2020	05/05/2020	07/05/2020	12/05/2020	12/05/2020	14/05/2020
B40	30/04/2020	14/05/2020	27/05/2020	29/05/2020	02/06/2020	02/06/2020	03/06/2020	04/06/2020	09/06/2020	09/06/2020	11/06/2020
B41	29/05/2020	11/06/2020	24/06/2020	26/06/2020	29/06/2020	29/06/2020	30/06/2020	02/07/2020	07/07/2020	07/07/2020	09/07/2020
B42											
B43	24/07/2020	07/08/2020	19/08/2020	21/08/2020	24/08/2020	24/08/2020	25/08/2020	27/08/2020	02/09/2020	02/09/2020	04/09/2020
B44	21/08/2020	03/09/2020	16/09/2020	18/09/2020	21/09/2020	21/09/2020	22/09/2020	24/09/2020	29/09/2020	29/09/2020	01/10/2020
B45	18/09/2020	01/10/2020	14/10/2020	16/10/2020	19/10/2020	19/10/2020	20/10/2020	22/10/2020	27/10/2020	27/10/2020	29/10/2020
B46	16/10/2020	29/10/2020	11/11/2020	13/11/2020	16/11/2020	16/11/2020	17/11/2020	19/11/2020	24/11/2020	24/11/2020	26/11/2020
B47	27/11/2020	17/12/2020	04/01/2021	04/01/2021	06/01/2021	06/01/2021	07/01/2021	07/01/2021	12/01/2021	12/01/2021	14/01/2021
B48	23/12/2020	14/01/2021	27/01/2021	29/01/2021	01/02/2021	01/02/2021	02/02/2021	04/02/2021	09/02/2021	09/02/2021	11/02/2021
B49	29/01/2021	11/02/2021	24/02/2021	26/02/2021	01/03/2021	01/03/2021	02/03/2021	04/03/2021	09/03/2021	09/03/2021	11/03/2021
B50	26/02/2021	12/03/2021	24/03/2021	26/03/2021	29/03/2021	29/03/2021	30/03/2021	31/03/2021	07/04/2021	07/04/2021	09/04/2021

	Submission deadline (*)	Start date (^)	CHMP Rapporteur AR (~)	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CHMP (**)	Updated PRAC Rapporteur AR (***)	Updated CHMP Rapporteur AR (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
B51	26/03/2021	08/04/2021	21/04/2021	23/04/2021	26/04/2021	26/04/2021	27/04/2021	29/04/2021	04/05/2021	04/05/2021	06/05/2021
B52	30/04/2021	13/05/2021	26/05/2021	28/05/2021	31/05/2021	31/05/2021	01/06/2021	03/06/2021	08/06/2021	08/06/2021	10/06/2021
B53	28/05/2021	10/06/2021	23/06/2021	25/06/2021	28/06/2021	28/06/2021	29/06/2021	01/07/2021	06/07/2021	06/07/2021	08/07/2021
B54											
B55	23/07/2021	06/08/2021	18/08/2021	20/08/2021	23/08/2021	23/08/2021	24/08/2021	26/08/2021	01/09/2021	01/09/2021	03/09/2021
B56	20/08/2021	02/09/2021	15/09/2021	17/09/2021	20/09/2021	20/09/2021	21/09/2021	23/09/2021	28/09/2021	28/09/2021	30/09/2021
B57	17/09/2021	30/09/2021	13/10/2021	15/10/2021	18/10/2021	18/10/2021	19/10/2021	21/10/2021	26/10/2021	26/10/2021	28/10/2021
B58	22/10/2021	04/11/2021	17/11/2021	19/11/2021	22/11/2021	22/11/2021	23/11/2021	25/11/2021	30/11/2021	30/11/2021	02/12/2021

(-) This timetable applies to the initial assessment of relatively urgent safety variations agreed upfront to be assessed in a short timeframe. It applies to PRAC-involving variations which do not lead to an immediate EC Decision after Opinion (mainly variations for addition of/changes to indications, for new contraindications, for changes in posology or variations with a DHPC) and which are not expected to require a discussion during the CHMP plenary meeting. The Agency will advise whether an immediate EC Decision or a CHMP discussion is required.

for the use of the alternative monthly timetable (please refer to the footnote of the 60-day timetable above).

(*) 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 not applicable in case of PRAC-led variation (i.e. one including only an RMP update and/or a non-interventional PASS without consequence to the SmPC and PL).

(**) 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.

(#) Adoption of the outcome (Opinion or RSI) via written procedure is necessary when the adoption occurs outside of the CHMP plenary meeting.

60-day responses (after clockstop) 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 (***) (~)	PRAC outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
C1	03/02/2017	07/02/2017	13/03/2017	20/03/2017	24/03/2017	27/03/2017	28/03/2017	30/03/2017	04/04/2017	04/04/2017	06/04/2017
C2	03/03/2017	08/03/2017	11/04/2017	19/04/2017	24/04/2017	25/04/2017	26/04/2017	28/04/2017	03/05/2017	03/05/2017	05/05/2017
C3	07/04/2017	12/04/2017	16/05/2017	23/05/2017	30/05/2017	31/05/2017	01/06/2017	02/06/2017	07/06/2017	07/06/2017	09/06/2017
C4	05/05/2017	09/05/2017	12/06/2017	19/06/2017	23/06/2017	26/06/2017	27/06/2017	29/06/2017	04/07/2017	04/07/2017	06/07/2017
C5											
C6	30/06/2017	05/07/2017	08/08/2017	15/08/2017	18/08/2017	22/08/2017	23/08/2017	25/08/2017	30/08/2017	30/08/2017	01/09/2017
C7	28/07/2017	01/08/2017	04/09/2017	11/09/2017	15/09/2017	18/09/2017	19/09/2017	21/09/2017	26/09/2017	26/09/2017	28/09/2017
C8	25/08/2017	29/08/2017	02/10/2017	09/10/2017	13/10/2017	16/10/2017	17/10/2017	19/10/2017	24/10/2017	24/10/2017	26/10/2017
C9	29/09/2017	03/10/2017	06/11/2017	13/11/2017	17/11/2017	20/11/2017	21/11/2017	23/11/2017	28/11/2017	28/11/2017	30/11/2017
C10	10/11/2017	15/11/2017	14/12/2017	21/12/2017	03/01/2018	03/01/2018	04/01/2018	05/01/2018	09/01/2018	09/01/2018	11/01/2018
C11	08/12/2017	12/12/2017	15/01/2018	22/01/2018	26/01/2018	29/01/2018	30/01/2018	01/02/2018	06/02/2018	06/02/2018	08/02/2018
C12	05/01/2018	09/01/2018	12/02/2018	19/02/2018	23/02/2018	26/02/2018	27/02/2018	01/03/2018	06/03/2018	06/03/2018	08/03/2018
C13	09/02/2018	13/02/2018	19/03/2018	26/03/2018	03/04/2018	03/04/2018	04/04/2018	05/04/2018	10/04/2018	10/04/2018	12/04/2018
C14	16/03/2018	21/03/2018	20/04/2018	27/04/2018	02/05/2018	04/05/2018	07/05/2018	08/05/2018	15/05/2018	15/05/2018	17/05/2018
C15	13/04/2018	17/04/2018	22/05/2018	28/05/2018	01/06/2018	04/06/2018	05/06/2018	07/06/2018	12/06/2018	12/06/2018	14/06/2018
C16	08/05/2018	15/05/2018	18/06/2018	25/06/2018	29/06/2018	02/07/2018	03/07/2018	05/07/2018	10/07/2018	10/07/2018	12/07/2018
C17											
C18	06/07/2018	10/07/2018	13/08/2018	20/08/2018	24/08/2018	28/08/2018	28/08/2018	30/08/2018	04/09/2018	04/09/2018	06/09/2018
C19	03/08/2018	07/08/2018	10/09/2018	17/09/2018	21/09/2018	24/09/2018	25/09/2018	27/09/2018	02/10/2018	02/10/2018	04/10/2018
C20	30/08/2018	03/09/2018	08/10/2018	15/10/2018	18/10/2018	19/10/2018	22/10/2018	24/10/2018	29/10/2018	29/10/2018	31/10/2018
C21	28/09/2018	02/10/2018	05/11/2018	12/11/2018	16/11/2018	19/11/2018	20/11/2018	22/11/2018	27/11/2018	27/11/2018	29/11/2018
C22	19/11/2018	20/11/2018	20/12/2018	03/01/2019	07/01/2019	07/01/2019	09/01/2019	10/01/2019	15/01/2019	15/01/2019	17/01/2019
C23	17/12/2018	18/12/2018	21/01/2019	28/01/2019	01/02/2019	04/02/2019	05/02/2019	07/02/2019	12/02/2019	12/02/2019	14/02/2019
C24	14/01/2019	15/01/2019	18/02/2019	25/02/2019	01/03/2019	04/03/2019	05/03/2019	07/03/2019	12/03/2019	12/03/2019	14/03/2019

	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 (***) (~)	PRAC outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
C25	11/02/2019	12/02/2019	18/03/2019	25/03/2019	29/03/2019	01/04/2019	02/04/2019	04/04/2019	09/04/2019	09/04/2019	11/04/2019
C26	18/03/2019	19/03/2019	23/04/2019	29/04/2019	03/05/2019	06/05/2019	07/05/2019	08/05/2019	14/05/2019	14/05/2019	16/05/2019
C27	16/04/2019	17/04/2019	20/05/2019	27/05/2019	03/06/2019	03/06/2019	05/06/2019	06/06/2019	12/06/2019	12/06/2019	14/06/2019
C28	13/05/2019	14/05/2019	17/06/2019	24/06/2019	28/06/2019	01/07/2019	02/07/2019	04/07/2019	09/07/2019	09/07/2019	11/07/2019
C29											
C30	08/07/2019	09/07/2019	12/08/2019	19/08/2019	23/08/2019	27/08/2019	27/08/2019	29/08/2019	03/09/2019	03/09/2019	05/09/2019
C31	05/08/2019	06/08/2019	09/09/2019	16/09/2019	20/09/2019	23/09/2019	24/09/2019	26/09/2019	01/10/2019	01/10/2019	03/10/2019
C32	02/09/2019	03/09/2019	07/10/2019	14/10/2019	18/10/2019	21/10/2019	22/10/2019	24/10/2019	29/10/2019	29/10/2019	31/10/2019
C33	30/09/2019	01/10/2019	04/11/2019	11/11/2019	15/11/2019	18/11/2019	19/11/2019	21/11/2019	26/11/2019	26/11/2019	28/11/2019
C34	18/11/2019	19/11/2019	19/12/2019	03/01/2020	07/01/2020	07/01/2020	09/01/2020	09/01/2020	14/01/2020	14/01/2020	16/01/2020
C35	16/12/2019	17/12/2019	20/01/2020	27/01/2020	31/01/2020	03/02/2020	04/02/2020	06/02/2020	11/02/2020	11/02/2020	13/02/2020
C36	13/01/2020	14/01/2020	17/02/2020	24/02/2020	28/02/2020	02/03/2020	03/03/2020	05/03/2020	10/03/2020	10/03/2020	12/03/2020
C37	18/02/2020	19/02/2020	23/03/2020	30/03/2020	03/04/2020	06/04/2020	07/04/2020	08/04/2020	15/04/2020	15/04/2020	17/04/2020
C38	16/03/2020	17/03/2020	20/04/2020	27/04/2020	04/05/2020	04/05/2020	06/05/2020	07/05/2020	12/05/2020	12/05/2020	14/05/2020
C39	08/04/2020	14/04/2020	18/05/2020	25/05/2020	29/05/2020	02/06/2020	02/06/2020	04/06/2020	09/06/2020	09/06/2020	11/06/2020
C40	11/05/2020	12/05/2020	15/06/2020	22/06/2020	26/06/2020	29/06/2020	30/06/2020	02/07/2020	07/07/2020	07/07/2020	09/07/2020
C41											
C42	07/07/2020	08/07/2020	10/08/2020	17/08/2020	21/08/2020	24/08/2020	25/08/2020	27/08/2020	02/09/2020	02/09/2020	04/09/2020
C43	03/08/2020	04/08/2020	07/09/2020	14/09/2020	18/09/2020	21/09/2020	22/09/2020	24/09/2020	29/09/2020	29/09/2020	01/10/2020
C44	28/08/2020	01/09/2020	05/10/2020	12/10/2020	16/10/2020	19/10/2020	20/10/2020	22/10/2020	27/10/2020	27/10/2020	29/10/2020
C45	28/09/2020	29/09/2020	03/11/2020	09/11/2020	13/11/2020	16/11/2020	17/11/2020	19/11/2020	24/11/2020	24/11/2020	26/11/2020
C46	16/11/2020	17/11/2020	18/12/2020	21/12/2020	05/01/2021	06/01/2021	07/01/2021	07/01/2021	12/01/2021	12/01/2021	14/01/2021
C47	14/12/2020	15/12/2020	18/01/2021	25/01/2021	29/01/2021	01/02/2021	02/02/2021	04/02/2021	09/02/2021	09/02/2021	11/02/2021
C48	11/01/2021	12/01/2021	15/02/2021	22/02/2021	26/02/2021	01/03/2021	02/03/2021	04/03/2021	09/03/2021	09/03/2021	11/03/2021
C49	09/02/2021	10/02/2021	15/03/2021	22/03/2021	26/03/2021	29/03/2021	30/03/2021	31/03/2021	07/04/2021	07/04/2021	09/04/2021
C50	08/03/2021	09/03/2021	12/04/2021	19/04/2021	23/04/2021	26/04/2021	27/04/2021	29/04/2021	04/05/2021	04/05/2021	06/05/2021

	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 (***) (~)	PRAC outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
C51	12/04/2021	13/04/2021	17/05/2021	25/05/2021	28/05/2021	31/05/2021	01/06/2021	03/06/2021	08/06/2021	08/06/2021	10/06/2021
C52	10/05/2021	11/05/2021	14/06/2021	21/06/2021	25/06/2021	28/06/2021	29/06/2021	01/07/2021	06/07/2021	06/07/2021	08/07/2021
C53											
C54	06/07/2021	07/07/2021	09/08/2021	16/08/2021	20/08/2021	23/08/2021	24/08/2021	26/08/2021	01/09/2021	01/09/2021	03/09/2021
C55	02/08/2021	03/08/2021	06/09/2021	13/09/2021	17/09/2021	20/09/2021	21/09/2021	23/09/2021	28/09/2021	28/09/2021	30/09/2021
C56	27/08/2021	31/08/2021	04/10/2021	11/10/2021	15/10/2021	18/10/2021	19/10/2021	21/10/2021	26/10/2021	26/10/2021	28/10/2021
C57	04/10/2021	05/10/2021	08/11/2021	15/11/2021	19/11/2021	22/11/2021	23/11/2021	25/11/2021	30/11/2021	30/11/2021	02/12/2021

(~) 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 not applicable in case of PRAC-led variation (i.e. one including only an RMP update and/or results of a non-interventional PASS without consequence to the SmPC and PL).

(**) 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.

(#) Adoption of the outcome (Opinion or RSI) via written procedure is necessary when the adoption occurs outside of the CHMP plenary meeting.

30-day responses (after clockstop) assessment timetable

	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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
D1	10/01/2017	12/01/2017	25/01/2017	27/01/2017	30/01/2017	30/01/2017	31/01/2017	02/02/2017	07/02/2017	07/02/2017	09/02/2017
D2	07/02/2017	09/02/2017	22/02/2017	24/02/2017	27/02/2017	27/02/2017	28/02/2017	02/03/2017	07/03/2017	07/03/2017	09/03/2017
D3	07/03/2017	09/03/2017	22/03/2017	24/03/2017	27/03/2017	27/03/2017	28/03/2017	30/03/2017	04/04/2017	04/04/2017	06/04/2017
D4	05/04/2017	07/04/2017	20/04/2017	21/04/2017	25/04/2017	25/04/2017	26/04/2017	28/04/2017	03/05/2017	03/05/2017	05/05/2017
D5	10/05/2017	12/05/2017	22/05/2017	24/05/2017	30/05/2017	30/05/2017	31/05/2017	02/06/2017	07/06/2017	07/06/2017	09/06/2017
D6	06/06/2017	08/06/2017	21/06/2017	23/06/2017	26/06/2017	26/06/2017	27/06/2017	29/06/2017	04/07/2017	04/07/2017	06/07/2017
D7											
D8	02/08/2017	04/08/2017	17/08/2017	18/08/2017	22/08/2017	22/08/2017	23/08/2017	25/08/2017	30/08/2017	30/08/2017	01/09/2017
D9	29/08/2017	31/08/2017	13/09/2017	15/09/2017	18/09/2017	18/09/2017	19/09/2017	21/09/2017	26/09/2017	26/09/2017	28/09/2017
D10	26/09/2017	28/09/2017	11/10/2017	13/10/2017	16/10/2017	16/10/2017	17/10/2017	19/10/2017	24/10/2017	24/10/2017	26/10/2017
D11	31/10/2017	02/11/2017	15/11/2017	17/11/2017	20/11/2017	20/11/2017	21/11/2017	23/11/2017	28/11/2017	28/11/2017	30/11/2017
D12	13/12/2017	15/12/2017	21/12/2017	03/01/2018	04/01/2018	04/01/2018	05/01/2018	05/01/2018	09/01/2018	09/01/2018	11/01/2018
D13	09/01/2018	11/01/2018	24/01/2018	26/01/2018	29/01/2018	29/01/2018	30/01/2018	01/02/2018	06/02/2018	06/02/2018	08/02/2018
D14	06/02/2018	08/02/2018	21/02/2018	23/02/2018	26/02/2018	26/02/2018	27/02/2018	01/03/2018	06/03/2018	06/03/2018	08/03/2018
D15	13/03/2018	15/03/2018	28/03/2018	03/04/2018	04/04/2018	04/04/2018	05/04/2018	05/04/2018	10/04/2018	10/04/2018	12/04/2018
D16	18/04/2018	20/04/2018	30/04/2018	03/05/2018	07/05/2018	07/05/2018	08/05/2018	08/05/2018	15/05/2018	15/05/2018	17/05/2018
D17	15/05/2018	17/05/2018	30/05/2018	01/06/2018	04/06/2018	04/06/2018	05/06/2018	07/06/2018	12/06/2018	12/06/2018	14/06/2018
D18	12/06/2018	14/06/2018	27/06/2018	29/06/2018	02/07/2018	02/07/2018	03/07/2018	05/07/2018	10/07/2018	10/07/2018	12/07/2018
D19											
D20	07/08/2018	09/08/2018	22/08/2018	24/08/2018	28/08/2018	28/08/2018	29/08/2018	30/08/2018	04/09/2018	04/09/2018	06/09/2018
D21	04/09/2018	06/09/2018	19/09/2018	21/09/2018	24/09/2018	24/09/2018	25/09/2018	27/09/2018	02/10/2018	02/10/2018	04/10/2018
D22	01/10/2018	03/10/2018	16/10/2018	18/10/2018	22/10/2018	22/10/2018	24/10/2018	25/10/2018	29/10/2018	29/10/2018	31/10/2018
D23	30/10/2018	01/11/2018	14/11/2018	16/11/2018	19/11/2018	19/11/2018	20/11/2018	22/11/2018	27/11/2018	27/11/2018	29/11/2018
D24	18/12/2018	20/12/2018	03/01/2019	07/01/2019	09/01/2019	09/01/2019	10/01/2019	10/01/2019	15/01/2019	15/01/2019	17/01/2019

	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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
D25	15/01/2019	17/01/2019	30/01/2019	01/02/2019	04/02/2019	04/02/2019	05/02/2019	07/02/2019	12/02/2019	12/02/2019	14/02/2019
D26	12/02/2019	14/02/2019	27/02/2019	01/03/2019	04/03/2019	04/03/2019	05/03/2019	07/03/2019	12/03/2019	12/03/2019	14/03/2019
D27	12/03/2019	14/03/2019	27/03/2019	29/03/2019	01/04/2019	01/04/2019	02/04/2019	04/04/2019	09/04/2019	09/04/2019	11/04/2019
D28	16/04/2019	18/04/2019	30/04/2019	03/05/2019	06/05/2019	06/05/2019	07/05/2019	08/05/2019	14/05/2019	14/05/2019	16/05/2019
D29	15/05/2019	17/05/2019	29/05/2019	29/05/2019	03/06/2019	03/06/2019	04/06/2019	06/06/2019	12/06/2019	12/06/2019	14/06/2019
D30	11/06/2019	13/06/2019	26/06/2019	28/06/2019	01/07/2019	01/07/2019	02/07/2019	04/07/2019	09/07/2019	09/07/2019	11/07/2019
D31											
D32	06/08/2019	08/08/2019	21/08/2019	23/08/2019	27/08/2019	27/08/2019	28/08/2019	29/08/2019	03/09/2019	03/09/2019	05/09/2019
D33	03/09/2019	05/09/2019	18/09/2019	20/09/2019	23/09/2019	23/09/2019	24/09/2019	26/09/2019	01/10/2019	01/10/2019	03/10/2019
D34	01/10/2019	03/10/2019	16/10/2019	18/10/2019	21/10/2019	21/10/2019	22/10/2019	24/10/2019	29/10/2019	29/10/2019	31/10/2019
D35	29/10/2019	31/10/2019	13/11/2019	15/11/2019	18/11/2019	18/11/2019	19/11/2019	21/11/2019	26/11/2019	26/11/2019	28/11/2019
D36	17/12/2019	19/12/2019	03/01/2020	07/01/2020	09/01/2020	09/01/2020	10/01/2020	10/01/2020	14/01/2020	14/01/2020	16/01/2020
D37	14/01/2020	16/01/2020	29/01/2020	31/01/2020	03/02/2020	03/02/2020	04/02/2020	06/02/2020	11/02/2020	11/02/2020	13/02/2020
D38	11/02/2020	13/02/2020	26/02/2020	28/02/2020	02/03/2020	02/03/2020	03/03/2020	05/03/2020	10/03/2020	10/03/2020	12/03/2020
D39	18/03/2020	20/03/2020	01/04/2020	03/04/2020	06/04/2020	06/04/2020	07/04/2020	08/04/2020	15/04/2020	15/04/2020	17/04/2020
D40	14/04/2020	16/04/2020	29/04/2020	30/04/2020	04/05/2020	04/05/2020	05/05/2020	07/05/2020	12/05/2020	12/05/2020	14/05/2020
D41	12/05/2020	14/05/2020	27/05/2020	29/05/2020	02/06/2020	02/06/2020	03/06/2020	04/06/2020	09/06/2020	09/06/2020	11/06/2020
D42	09/06/2020	11/06/2020	24/06/2020	26/06/2020	29/06/2020	29/06/2020	30/06/2020	02/07/2020	07/07/2020	07/07/2020	09/07/2020
D43											
D44	05/08/2020	07/08/2020	19/08/2020	21/08/2020	24/08/2020	24/08/2020	25/08/2020	27/08/2020	02/09/2020	02/09/2020	04/09/2020
D45	01/09/2020	03/09/2020	16/09/2020	18/09/2020	21/09/2020	21/09/2020	22/09/2020	24/09/2020	29/09/2020	29/09/2020	01/10/2020
D46	29/09/2020	01/10/2020	14/10/2020	16/10/2020	19/10/2020	19/10/2020	20/10/2020	22/10/2020	27/10/2020	27/10/2020	29/10/2020
D47	27/10/2020	29/10/2020	11/11/2020	13/11/2020	16/11/2020	16/11/2020	17/11/2020	19/11/2020	24/11/2020	24/11/2020	26/11/2020
D48	15/12/2020	17/12/2020	04/01/2021	04/01/2021	06/01/2021	06/01/2021	07/01/2021	07/01/2021	12/01/2021	12/01/2021	14/01/2021
D49	12/01/2021	14/01/2021	27/01/2021	29/01/2021	01/02/2021	01/02/2021	02/02/2021	04/02/2021	09/02/2021	09/02/2021	11/02/2021
D50	09/02/2021	11/02/2021	24/02/2021	26/02/2021	01/03/2021	01/03/2021	02/03/2021	04/03/2021	09/03/2021	09/03/2021	11/03/2021

	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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
D51	10/03/2021	12/03/2021	24/03/2021	26/03/2021	29/03/2021	29/03/2021	30/03/2021	31/03/2021	07/04/2021	07/04/2021	09/04/2021
D52	06/04/2021	08/04/2021	21/04/2021	23/04/2021	26/04/2021	26/04/2021	27/04/2021	29/04/2021	04/05/2021	04/05/2021	06/05/2021
D53	11/05/2021	13/05/2021	26/05/2021	28/05/2021	31/05/2021	31/05/2021	01/06/2021	03/06/2021	08/06/2021	08/06/2021	10/06/2021
D54	08/06/2021	10/06/2021	23/06/2021	25/06/2021	28/06/2021	28/06/2021	29/06/2021	01/07/2021	06/07/2021	06/07/2021	08/07/2021
D55											
D56	04/08/2021	06/08/2021	18/08/2021	20/08/2021	23/08/2021	23/08/2021	24/08/2021	26/08/2021	01/09/2021	01/09/2021	03/09/2021
D57	31/08/2021	02/09/2021	15/09/2021	17/09/2021	20/09/2021	20/09/2021	21/09/2021	23/09/2021	28/09/2021	28/09/2021	30/09/2021
D58	28/09/2021	30/09/2021	13/10/2021	15/10/2021	18/10/2021	18/10/2021	19/10/2021	21/10/2021	26/10/2021	26/10/2021	28/10/2021
D59	29/10/2021	04/11/2021	17/11/2021	19/11/2021	22/11/2021	22/11/2021	23/11/2021	25/11/2021	30/11/2021	30/11/2021	02/12/2021

(~) 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 not applicable in case of PRAC-led variation (i.e. one including only an RMP update and/or a non-interventional PASS without consequence to the SmPC and PL).

(**) 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.

(#) Adoption of the outcome (Opinion or RSI) via written procedure is necessary when the adoption occurs outside of the CHMP plenary meeting.

30-day immediate responses 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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
E1	17/01/2017	19/01/2017	25/01/2017	25/01/2017	30/01/2017	30/01/2017	02/02/2017	02/02/2017	07/02/2017	07/02/2017	09/02/2017
E2	14/02/2017	16/02/2017	22/02/2017	22/02/2017	27/02/2017	27/02/2017	02/03/2017	02/03/2017	07/03/2017	07/03/2017	09/03/2017
E3	14/03/2017	16/03/2017	22/03/2017	22/03/2017	27/03/2017	27/03/2017	30/03/2017	30/03/2017	04/04/2017	04/04/2017	06/04/2017
E4	12/04/2017	14/04/2017	20/04/2017	20/04/2017	25/04/2017	25/04/2017	28/04/2017	28/04/2017	03/05/2017	03/05/2017	05/05/2017
E5	17/05/2017	19/05/2017	24/05/2017	24/05/2017	30/05/2017	30/05/2017	02/06/2017	02/06/2017	07/06/2017	07/06/2017	09/06/2017
E6	13/06/2017	15/06/2017	21/06/2017	21/06/2017	26/06/2017	26/06/2017	29/06/2017	29/06/2017	04/07/2017	04/07/2017	06/07/2017
E7											
E8											
E9	05/09/2017	07/09/2017	13/09/2017	13/09/2017	18/09/2017	18/09/2017	21/09/2017	21/09/2017	26/09/2017	26/09/2017	28/09/2017
E10	03/10/2017	05/10/2017	11/10/2017	11/10/2017	16/10/2017	16/10/2017	19/10/2017	19/10/2017	24/10/2017	24/10/2017	26/10/2017
E11	07/11/2017	09/11/2017	15/11/2017	15/11/2017	20/11/2017	20/11/2017	23/11/2017	23/11/2017	28/11/2017	28/11/2017	30/11/2017
E12	19/12/2017	21/12/2017	21/12/2017	03/01/2018	04/01/2018	04/01/2018	05/01/2018	05/01/2018	09/01/2018	09/01/2018	11/01/2018
E13	16/01/2018	18/01/2018	24/01/2018	24/01/2018	29/01/2018	29/01/2018	01/02/2018	01/02/2018	06/02/2018	06/02/2018	08/02/2018
E14	13/02/2018	15/02/2018	21/02/2018	21/02/2018	26/02/2018	26/02/2018	01/03/2018	01/03/2018	06/03/2018	06/03/2018	08/03/2018
E15	15/03/2018	16/03/2018	28/03/2018	28/03/2018	04/04/2018	04/04/2018	05/04/2018	05/04/2018	10/04/2018	10/04/2018	12/04/2018
E16	19/04/2018	20/04/2018	30/04/2018	30/04/2018	07/05/2018	07/05/2018	08/05/2018	08/05/2018	15/05/2018	15/05/2018	17/05/2018
E17	22/05/2018	24/05/2018	30/05/2018	30/05/2018	04/06/2018	04/06/2018	07/06/2018	07/06/2018	12/06/2018	12/06/2018	14/06/2018
E18	19/06/2018	21/06/2018	27/06/2018	27/06/2018	02/07/2018	02/07/2018	05/07/2018	05/07/2018	10/07/2018	10/07/2018	12/07/2018
E19											
E20											
E21	11/09/2018	13/09/2018	19/09/2018	19/09/2018	24/09/2018	24/09/2018	27/09/2018	27/09/2018	02/10/2018	02/10/2018	04/10/2018
E22	08/10/2018	10/10/2018	16/10/2018	16/10/2018	22/10/2018	22/10/2018	24/10/2018	24/10/2018	29/10/2018	29/10/2018	31/10/2018
E23	06/11/2018	08/11/2018	14/11/2018	14/11/2018	19/11/2018	19/11/2018	22/11/2018	22/11/2018	27/11/2018	27/11/2018	29/11/2018
E24	20/12/2018	26/12/2018	03/01/2019	03/01/2019	09/01/2019	09/01/2019	10/01/2019	10/01/2019	15/01/2019	15/01/2019	17/01/2019

	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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
E25	22/01/2019	23/01/2019	30/01/2019	30/01/2019	04/02/2019	04/02/2019	07/02/2019	07/02/2019	12/02/2019	12/02/2019	14/02/2019
E26	19/02/2019	20/02/2019	27/02/2019	27/02/2019	04/03/2019	04/03/2019	07/03/2019	07/03/2019	12/03/2019	12/03/2019	14/03/2019
E27	19/03/2019	20/03/2019	27/03/2019	27/03/2019	01/04/2019	01/04/2019	04/04/2019	04/04/2019	09/04/2019	09/04/2019	11/04/2019
E28	18/04/2019	24/04/2019	30/04/2019	30/04/2019	06/05/2019	06/05/2019	08/05/2019	08/05/2019	14/05/2019	14/05/2019	16/05/2019
E29	22/05/2019	23/05/2019	29/05/2019	29/05/2019	03/06/2019	03/06/2019	06/06/2019	06/06/2019	12/06/2019	12/06/2019	14/06/2019
E30	18/06/2019	19/06/2019	26/06/2019	26/06/2019	01/07/2019	01/07/2019	04/07/2019	04/07/2019	09/07/2019	09/07/2019	11/07/2019
E31											
E32											
E33	10/09/2019	11/09/2019	18/09/2019	18/09/2019	23/09/2019	23/09/2019	26/09/2019	26/09/2019	01/10/2019	01/10/2019	03/10/2019
E34	08/10/2019	09/10/2019	16/10/2019	16/10/2019	21/10/2019	21/10/2019	24/10/2019	24/10/2019	29/10/2019	29/10/2019	31/10/2019
E35	05/11/2019	06/11/2019	13/11/2019	13/11/2019	18/11/2019	18/11/2019	21/11/2019	21/11/2019	26/11/2019	26/11/2019	28/11/2019
E36	19/12/2019	25/12/2019	03/01/2020	03/01/2020	09/01/2020	09/01/2020	10/01/2020	10/01/2020	14/01/2020	14/01/2020	16/01/2020
E37	21/01/2020	22/01/2020	29/01/2020	29/01/2020	03/02/2020	03/02/2020	06/02/2020	06/02/2020	11/02/2020	11/02/2020	13/02/2020
E38	18/02/2020	19/02/2020	26/02/2020	26/02/2020	02/03/2020	02/03/2020	05/03/2020	05/03/2020	10/03/2020	10/03/2020	12/03/2020
E39	19/03/2020	26/03/2020	01/04/2020	01/04/2020	06/04/2020	06/04/2020	08/04/2020	08/04/2020	15/04/2020	15/04/2020	17/04/2020
E40	21/04/2020	22/04/2020	29/04/2020	29/04/2020	04/05/2020	04/05/2020	07/05/2020	07/05/2020	12/05/2020	12/05/2020	14/05/2020
E41	19/05/2020	20/05/2020	27/05/2020	27/05/2020	02/06/2020	02/06/2020	04/06/2020	04/06/2020	09/06/2020	09/06/2020	11/06/2020
E42	16/06/2020	17/06/2020	24/06/2020	24/06/2020	29/06/2020	29/06/2020	02/07/2020	02/07/2020	07/07/2020	07/07/2020	09/07/2020
E43											
E44											
E45	08/09/2020	09/09/2020	16/09/2020	16/09/2020	21/09/2020	21/09/2020	24/09/2020	24/09/2020	29/09/2020	29/09/2020	01/10/2020
E46	06/10/2020	07/10/2020	14/10/2020	14/10/2020	19/10/2020	19/10/2020	22/10/2020	22/10/2020	27/10/2020	27/10/2020	29/10/2020
E47	03/11/2020	04/11/2020	11/11/2020	11/11/2020	16/11/2020	16/11/2020	19/11/2020	19/11/2020	24/11/2020	24/11/2020	26/11/2020
E48	17/12/2020	23/12/2020	04/01/2021	04/01/2021	06/01/2021	06/01/2021	07/01/2021	07/01/2021	12/01/2021	12/01/2021	14/01/2021
E49	19/01/2021	20/01/2021	27/01/2021	27/01/2021	01/02/2021	01/02/2021	04/02/2021	04/02/2021	09/02/2021	09/02/2021	11/02/2021
E50	16/02/2021	17/02/2021	24/02/2021	24/02/2021	01/03/2021	01/03/2021	04/03/2021	04/03/2021	09/03/2021	09/03/2021	11/03/2021

	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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
E51	17/03/2021	18/03/2021	24/03/2021	24/03/2021	29/03/2021	29/03/2021	31/03/2021	31/03/2021	07/04/2021	07/04/2021	09/04/2021
E52	13/04/2021	14/04/2021	21/04/2021	21/04/2021	26/04/2021	26/04/2021	29/04/2021	29/04/2021	04/05/2021	04/05/2021	06/05/2021
E53	13/05/2021	19/05/2021	26/05/2021	26/05/2021	31/05/2021	31/05/2021	03/06/2021	03/06/2021	08/06/2021	08/06/2021	10/06/2021
E54	15/06/2021	16/06/2021	23/06/2021	23/06/2021	28/06/2021	28/06/2021	01/07/2021	01/07/2021	06/07/2021	06/07/2021	08/07/2021
E55											
E56											
E57	07/09/2021	08/09/2021	15/09/2021	15/09/2021	20/09/2021	20/09/2021	23/09/2021	23/09/2021	28/09/2021	28/09/2021	30/09/2021
E58	05/10/2021	06/10/2021	13/10/2021	13/10/2021	18/10/2021	18/10/2021	21/10/2021	21/10/2021	26/10/2021	26/10/2021	28/10/2021
E59	04/11/2021	10/11/2021	17/11/2021	17/11/2021	22/11/2021	22/11/2021	25/11/2021	25/11/2021	30/11/2021	30/11/2021	02/12/2021

(~) 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 not applicable in case of PRAC-led variation (i.e. one including only an RMP update and/or a non-interventional PASS without consequence to the SmPC and PL.

(**) 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.

(#) Adoption of the outcome (Opinion or RSI) via written procedure is necessary when the adoption occurs outside of the CHMP plenary meeting.