



14 February 2022  
EMA/577387/2016 Rev.5  
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 timetable<sup>7</sup>

	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	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
A2	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
A3	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
A4	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
A5											
A6	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
A7	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
A8	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
A9	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
A10	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
A11	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
A12	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
A13	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
A14	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
A15	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
A16	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
A17											
A18	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
A19	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
A20	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
A21	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
A22	29/10/2021	16/11/2021	15/12/2021	22/12/2021	03/01/2022	03/01/2022	04/01/2022	06/01/2022	11/01/2022	11/01/2022	13/01/2022
A23	26/11/2021	14/12/2021	17/01/2022	24/01/2022	28/01/2022	31/01/2022	01/02/2022	03/02/2022	08/02/2022	08/02/2022	10/02/2022
A24	17/12/2021	11/01/2022	14/02/2022	21/02/2022	25/02/2022	28/02/2022	01/03/2022	03/03/2022	08/03/2022	08/03/2022	10/03/2022
A25	21/01/2022	08/02/2022	14/03/2022	21/03/2022	25/03/2022	28/03/2022	29/03/2022	31/03/2022	05/04/2022	05/04/2022	07/04/2022

	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
A26	18/02/2022	08/03/2022	11/04/2022	19/04/2022	22/04/2022	25/04/2022	26/04/2022	28/04/2022	03/05/2022	03/05/2022	05/05/2022
A27	25/03/2022	13/04/2022	16/05/2022	23/05/2022	25/05/2022	30/05/2022	31/05/2022	02/06/2022	08/06/2022	08/06/2022	10/06/2022
A28	22/04/2022	10/05/2022	13/06/2022	20/06/2022	24/06/2022	27/06/2022	28/06/2022	30/06/2022	05/07/2022	05/07/2022	07/07/2022
A29											
A30	17/06/2022	05/07/2022	08/08/2022	16/08/2022	19/08/2022	22/08/2022	23/08/2022	25/08/2022	30/08/2022	30/08/2022	01/09/2022
A31	15/07/2022	02/08/2022	05/09/2022	12/09/2022	16/09/2022	19/09/2022	20/09/2022	22/09/2022	27/09/2022	27/09/2022	29/09/2022
A32	12/08/2022	30/08/2022	03/10/2022	10/10/2022	14/10/2022	17/10/2022	18/10/2022	20/10/2022	25/10/2022	25/10/2022	27/10/2022
A33	16/09/2022	04/10/2022	07/11/2022	14/11/2022	18/11/2022	21/11/2022	22/11/2022	24/11/2022	29/11/2022	29/11/2022	01/12/2022
A34	28/10/2022	15/11/2022	15/12/2022	22/12/2022	03/01/2023	03/01/2023	04/01/2023	05/01/2023	10/01/2023	10/01/2023	12/01/2023
A35	25/11/2022	13/12/2022	16/01/2023	23/01/2023	27/01/2023	30/01/2023	31/01/2023	02/02/2023	07/02/2023	07/02/2023	09/02/2023
A36	22/12/2022	17/01/2023	20/02/2023	27/02/2023	03/03/2023	06/03/2023	07/03/2023	09/03/2023	14/03/2023	14/03/2023	16/03/2023
A37	27/01/2023	15/02/2023	20/03/2023	27/03/2023	31/03/2023	03/04/2023	04/04/2023	05/04/2023	12/04/2023	12/04/2023	14/04/2023
A38	24/02/2023	15/03/2023	17/04/2023	24/04/2023	28/04/2023	02/05/2023	03/05/2023	04/05/2023	10/05/2023	10/05/2023	12/05/2023
A39	24/03/2023	11/04/2023	15/05/2023	22/05/2023	26/05/2023	30/05/2023	31/05/2023	02/06/2023	06/06/2023	06/06/2023	08/06/2023
A40	21/04/2023	09/05/2023	12/06/2023	19/06/2023	23/06/2023	26/06/2023	27/06/2023	29/06/2023	04/07/2023	04/07/2023	06/07/2023
A41											
A42	16/06/2023	04/07/2023	07/08/2023	14/08/2023	18/08/2023	21/08/2023	22/08/2023	24/08/2023	29/08/2023	29/08/2023	31/08/2023
A43	14/07/2023	01/08/2023	04/09/2023	11/09/2023	15/09/2023	18/09/2023	19/09/2023	21/09/2023	26/09/2023	26/09/2023	28/09/2023
A44	11/08/2023	29/08/2023	02/10/2023	09/10/2023	13/10/2023	16/10/2023	17/10/2023	19/10/2023	24/10/2023	24/10/2023	26/10/2023
A45	15/09/2023	03/10/2023	06/11/2023	13/11/2023	17/11/2023	20/11/2023	21/11/2023	23/11/2023	28/11/2023	28/11/2023	30/11/2023
A46	27/10/2023	14/11/2023	14/12/2023	21/12/2023	03/01/2024	03/01/2024	04/01/2024	05/01/2024	09/01/2024	09/01/2024	11/01/2024
A47	24/11/2023	12/12/2023	15/01/2024	22/01/2024	26/01/2024	29/01/2024	30/01/2024	01/02/2024	06/02/2024	06/02/2024	08/02/2024
A48	15/12/2023	09/01/2024	12/02/2024	19/02/2024	23/02/2024	26/02/2024	27/02/2024	29/02/2024	05/03/2024	05/03/2024	07/03/2024
A49	26/01/2024	13/02/2024	18/03/2024	25/03/2024	27/03/2024	02/04/2024	02/04/2024	04/04/2024	09/04/2024	09/04/2024	11/04/2024
A50	01/03/2024	19/03/2024	22/04/2024	29/04/2024	03/05/2024	06/05/2024	07/05/2024	08/05/2024	14/05/2024	14/05/2024	16/05/2024
A51	27/03/2024	16/04/2024	21/05/2024	27/05/2024	31/05/2024	03/06/2024	04/06/2024	06/06/2024	11/06/2024	11/06/2024	13/06/2024
A52	26/04/2024	14/05/2024	17/06/2024	24/06/2024	28/06/2024	01/07/2024	02/07/2024	04/07/2024	09/07/2024	09/07/2024	11/07/2024

	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
A53											
A54	21/06/2024	09/07/2024	12/08/2024	19/08/2024	23/08/2024	26/08/2024	27/08/2024	29/08/2024	03/09/2024	03/09/2024	05/09/2024
A55	19/07/2024	06/08/2024	09/09/2024	16/09/2024	20/09/2024	23/09/2024	24/09/2024	26/09/2024	01/10/2024	01/10/2024	03/10/2024
A56	16/08/2024	03/09/2024	07/10/2024	14/10/2024	18/10/2024	21/10/2024	22/10/2024	24/10/2024	29/10/2024	29/10/2024	31/10/2024
A57	13/09/2024	01/10/2024	04/11/2024	11/11/2024	15/11/2024	18/11/2024	19/11/2024	21/11/2024	26/11/2024	26/11/2024	28/11/2024

(-) 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 timetable<sup>7</sup>

	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	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
B2	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
B3	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
B4	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
B5	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
B6	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
B7											
B8	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
B9	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
B10	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
B11	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
B12	04/12/2020	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
B13	22/12/2020	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
B14	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
B15	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
B16	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
B17	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
B18	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
B19											
B20	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
B21	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
B22	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
B23	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
B24	03/12/2021	16/12/2021	03/01/2022	03/01/2022	05/01/2022	05/01/2022	06/01/2022	07/01/2022	11/01/2022	11/01/2022	13/01/2022
B25	22/12/2021	13/01/2022	26/01/2022	28/01/2022	31/01/2022	31/01/2022	01/02/2022	03/02/2022	08/02/2022	08/02/2022	10/02/2022

	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
B26	28/01/2022	10/02/2022	23/02/2022	25/02/2022	28/02/2022	28/02/2022	01/03/2022	03/03/2022	08/03/2022	08/03/2022	10/03/2022
B27	25/02/2022	10/03/2022	23/03/2022	25/03/2022	28/03/2022	28/03/2022	29/03/2022	31/03/2022	05/04/2022	05/04/2022	07/04/2022
B28	25/03/2022	07/04/2022	20/04/2022	22/04/2022	25/04/2022	25/04/2022	26/04/2022	28/04/2022	03/05/2022	03/05/2022	05/05/2022
B29	29/04/2022	13/05/2022	25/05/2022	25/05/2022	30/05/2022	30/05/2022	31/05/2022	02/06/2022	07/06/2022	07/06/2022	10/06/2022
B30	25/05/2022	09/06/2022	22/06/2022	24/06/2022	27/06/2022	27/06/2022	28/06/2022	30/06/2022	05/07/2022	05/07/2022	07/07/2022
B31											
B32	22/07/2022	04/08/2022	17/08/2022	19/08/2022	22/08/2022	22/08/2022	23/08/2022	25/08/2022	30/08/2022	30/08/2022	01/09/2022
B33	19/08/2022	01/09/2022	14/09/2022	16/09/2022	19/09/2022	19/09/2022	20/09/2022	22/09/2022	27/09/2022	27/09/2022	29/09/2022
B34	16/09/2022	29/09/2022	12/10/2022	14/10/2022	17/10/2022	17/10/2022	18/10/2022	20/10/2022	25/10/2022	25/10/2022	27/10/2022
B35	14/10/2022	03/11/2022	16/11/2022	18/11/2022	21/11/2022	21/11/2022	22/11/2022	24/11/2022	29/11/2022	29/11/2022	01/12/2022
B36	11/11/2022	15/12/2022	03/01/2023	03/01/2023	05/01/2023	05/01/2023	06/01/2023	09/01/2023	10/01/2023	10/01/2023	12/01/2023
B37	22/12/2022	12/01/2023	25/01/2023	27/01/2023	30/01/2023	30/01/2023	31/01/2023	02/02/2023	07/02/2023	07/02/2023	09/02/2023
B38	03/02/2023	16/02/2023	01/03/2023	03/03/2023	06/03/2023	06/03/2023	07/03/2023	09/03/2023	14/03/2023	14/03/2023	16/03/2023
B39	03/03/2023	17/03/2023	29/03/2023	31/03/2023	03/04/2023	03/04/2023	04/04/2023	05/04/2023	11/04/2023	11/04/2023	14/04/2023
B40	31/03/2023	14/04/2023	26/04/2023	28/04/2023	02/05/2023	02/05/2023	03/05/2023	05/05/2023	10/05/2023	10/05/2023	12/05/2023
B41	28/04/2023	11/05/2023	24/05/2023	26/05/2023	30/05/2023	30/05/2023	31/05/2023	01/06/2023	06/06/2023	06/06/2023	08/06/2023
B42	26/05/2023	08/06/2023	21/06/2023	23/06/2023	26/06/2023	26/06/2023	27/06/2023	29/06/2023	04/07/2023	04/07/2023	06/07/2023
B43											
B44	21/07/2023	03/08/2023	16/08/2023	18/08/2023	21/08/2023	21/08/2023	22/08/2023	24/08/2023	29/08/2023	29/08/2023	31/08/2023
B45	18/08/2023	31/08/2023	13/09/2023	15/09/2023	18/09/2023	18/09/2023	19/09/2023	21/09/2023	26/09/2023	26/09/2023	28/09/2023
B46	15/09/2023	28/09/2023	11/10/2023	13/10/2023	16/10/2023	16/10/2023	17/10/2023	19/10/2023	24/10/2023	24/10/2023	26/10/2023
B47	20/10/2023	02/11/2023	15/11/2023	17/11/2023	20/11/2023	20/11/2023	21/11/2023	23/11/2023	28/11/2023	28/11/2023	30/11/2023
B48	01/12/2023	14/12/2023	03/01/2024	03/01/2024	04/01/2024	04/01/2024	05/01/2024	08/01/2024	09/01/2024	09/01/2024	11/01/2024
B49	21/12/2023	11/01/2024	24/01/2024	26/01/2024	29/01/2024	29/01/2024	30/01/2024	01/02/2024	06/02/2024	06/02/2024	08/02/2024
B50	26/01/2024	08/02/2024	21/02/2024	23/02/2024	26/02/2024	26/02/2024	27/02/2024	29/02/2024	05/03/2024	05/03/2024	07/03/2024
B51	01/03/2024	14/03/2024	27/03/2024	27/03/2024	02/04/2024	02/04/2024	03/04/2024	04/04/2024	09/04/2024	09/04/2024	11/04/2024
B52	05/04/2024	18/04/2024	02/05/2024	03/05/2024	06/05/2024	06/05/2024	07/05/2024	08/05/2024	14/05/2024	14/05/2024	16/05/2024

	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
B53	03/05/2024	16/05/2024	29/05/2024	31/05/2024	03/06/2024	03/06/2024	04/06/2024	06/06/2024	11/06/2024	11/06/2024	13/06/2024
B54	31/05/2024	13/06/2024	26/06/2024	28/06/2024	01/07/2024	01/07/2024	02/07/2024	04/07/2024	09/07/2024	09/07/2024	11/07/2024
B55											
B56	26/07/2024	08/08/2024	21/08/2024	23/08/2024	26/08/2024	26/08/2024	27/08/2024	29/08/2024	03/09/2024	03/09/2024	05/09/2024
B57	23/08/2024	05/09/2024	18/09/2024	20/09/2024	23/09/2024	23/09/2024	24/09/2024	26/09/2024	01/10/2024	01/10/2024	03/10/2024
B58	20/09/2024	03/10/2024	16/10/2024	18/10/2024	21/10/2024	21/10/2024	22/10/2024	24/10/2024	29/10/2024	29/10/2024	31/10/2024
B59	18/10/2024	31/10/2024	13/11/2024	15/11/2024	18/11/2024	18/11/2024	19/11/2024	21/11/2024	26/11/2024	26/11/2024	28/11/2024

(-) 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 timetable<sup>7</sup>

	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	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
C2	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
C3	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
C4	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
C5	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
C6											
C7	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
C8	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
C9	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
C10	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
C11	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
C12	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
C13	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
C14	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
C15	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
C16	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
C17	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
C18											
C19	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
C20	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
C21	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
C22	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
C23	15/11/2021	16/11/2021	15/12/2021	22/12/2021	03/01/2022	03/01/2022	04/01/2022	06/01/2022	11/01/2022	11/01/2022	13/01/2022
C24	13/12/2021	14/12/2021	17/01/2022	24/01/2022	28/01/2022	31/01/2022	01/02/2022	03/02/2022	08/02/2022	08/02/2022	10/02/2022
C25	10/01/2022	11/01/2022	14/02/2022	21/02/2022	25/02/2022	28/02/2022	01/03/2022	03/03/2022	08/03/2022	08/03/2022	10/03/2022



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

	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 (***) (~)	PRAC outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
C53	13/05/2024	14/05/2024	17/06/2024	24/06/2024	28/06/2024	01/07/2024	02/07/2024	04/07/2024	09/07/2024	09/07/2024	11/07/2024
C54											
C55	08/07/2024	09/07/2024	12/08/2024	19/08/2024	23/08/2024	26/08/2024	27/08/2024	29/08/2024	03/09/2024	03/09/2024	05/09/2024
C56	05/08/2024	06/08/2024	09/09/2024	16/09/2024	20/09/2024	23/09/2024	24/09/2024	26/09/2024	01/10/2024	01/10/2024	03/10/2024
C57	02/09/2024	03/09/2024	07/10/2024	14/10/2024	18/10/2024	21/10/2024	22/10/2024	24/10/2024	29/10/2024	29/10/2024	31/10/2024
C58	30/09/2024	01/10/2024	04/11/2024	11/11/2024	15/11/2024	18/11/2024	19/11/2024	21/11/2024	26/11/2024	26/11/2024	28/11/2024

(-) 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 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<sup>7</sup>

	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	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
D2	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
D3	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
D4	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
D5	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
D6	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
D7											
D8	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
D9	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
D10	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
D11	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
D12	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
D13	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
D14	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
D15	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
D16	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
D17	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
D18	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
D19											
D20	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
D21	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
D22	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
D23	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
D24	15/12/2021	16/12/2021	03/01/2022	03/01/2022	05/01/2022	05/01/2022	06/01/2022	06/01/2022	11/01/2022	11/01/2022	13/01/2022
D25	12/01/2022	13/01/2022	26/01/2022	28/01/2022	31/01/2022	31/01/2022	01/02/2022	03/02/2022	08/02/2022	08/02/2022	10/02/2022

	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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
D26	09/02/2022	10/02/2022	23/02/2022	25/02/2022	28/02/2022	28/02/2022	01/03/2022	03/03/2022	08/03/2022	08/03/2022	10/03/2022
D27	09/03/2022	10/03/2022	23/03/2022	25/03/2022	28/03/2022	28/03/2022	29/03/2022	31/03/2022	05/04/2022	05/04/2022	07/04/2022
D28	06/04/2022	07/04/2022	20/04/2022	22/04/2022	25/04/2022	25/04/2022	26/04/2022	28/04/2022	03/05/2022	03/05/2022	05/05/2022
D29	12/05/2022	13/05/2022	25/05/2022	25/05/2022	30/05/2022	30/05/2022	31/05/2022	02/06/2022	07/06/2022	07/06/2022	10/06/2022
D30	08/06/2022	09/06/2022	22/06/2022	24/06/2022	27/06/2022	27/06/2022	28/06/2022	30/06/2022	05/07/2022	05/07/2022	07/07/2022
D31											
D32	03/08/2022	04/08/2022	17/08/2022	19/08/2022	22/08/2022	22/08/2022	23/08/2022	25/08/2022	30/08/2022	30/08/2022	01/09/2022
D33	31/08/2022	01/09/2022	14/09/2022	16/09/2022	19/09/2022	19/09/2022	20/09/2022	22/09/2022	27/09/2022	27/09/2022	29/09/2022
D34	28/09/2022	29/09/2022	12/10/2022	14/10/2022	17/10/2022	17/10/2022	18/10/2022	20/10/2022	25/10/2022	25/10/2022	27/10/2022
D35	28/10/2022	03/11/2022	16/11/2022	18/11/2022	21/11/2022	21/11/2022	22/11/2022	24/11/2022	29/11/2022	29/11/2022	01/12/2022
D36	14/12/2022	15/12/2022	03/01/2023	03/01/2023	05/01/2023	05/01/2023	06/01/2023	06/01/2023	10/01/2023	10/01/2023	12/01/2023
D37	11/01/2023	12/01/2023	25/01/2023	27/01/2023	30/01/2023	30/01/2023	31/01/2023	02/02/2023	07/02/2023	07/02/2023	09/02/2023
D38	15/02/2023	16/02/2023	01/03/2023	03/03/2023	06/03/2023	06/03/2023	07/03/2023	09/03/2023	14/03/2023	14/03/2023	16/03/2023
D39	16/03/2023	17/03/2023	29/03/2023	31/03/2023	03/04/2023	03/04/2023	04/04/2023	05/04/2023	11/04/2023	11/04/2023	14/04/2023
D40	13/04/2023	14/04/2023	26/04/2023	28/04/2023	02/05/2023	02/05/2023	03/05/2023	05/05/2023	10/05/2023	10/05/2023	12/05/2023
D41	10/05/2023	11/05/2023	24/05/2023	26/05/2023	30/05/2023	30/05/2023	31/05/2023	01/06/2023	06/06/2023	06/06/2023	08/06/2023
D42	07/06/2023	08/06/2023	21/06/2023	23/06/2023	26/06/2023	26/06/2023	27/06/2023	29/06/2023	04/07/2023	04/07/2023	06/07/2023
D43											
D44	02/08/2023	03/08/2023	16/08/2023	18/08/2023	21/08/2023	21/08/2023	22/08/2023	24/08/2023	29/08/2023	29/08/2023	31/08/2023
D45	30/08/2023	31/08/2023	13/09/2023	15/09/2023	18/09/2023	18/09/2023	19/09/2023	21/09/2023	26/09/2023	26/09/2023	28/09/2023
D46	27/09/2023	28/09/2023	11/10/2023	13/10/2023	16/10/2023	16/10/2023	17/10/2023	19/10/2023	24/10/2023	24/10/2023	26/10/2023
D47	31/10/2023	02/11/2023	15/11/2023	17/11/2023	20/11/2023	20/11/2023	21/11/2023	23/11/2023	28/11/2023	28/11/2023	30/11/2023
D48	13/12/2023	14/12/2023	03/01/2024	03/01/2024	04/01/2024	04/01/2024	05/01/2024	04/01/2024	09/01/2024	09/01/2024	11/01/2024
D49	10/01/2024	11/01/2024	24/01/2024	26/01/2024	29/01/2024	29/01/2024	30/01/2024	01/02/2024	06/02/2024	06/02/2024	08/02/2024
D50	07/02/2024	08/02/2024	21/02/2024	23/02/2024	26/02/2024	26/02/2024	27/02/2024	29/02/2024	05/03/2024	05/03/2024	07/03/2024
D51	13/03/2024	14/03/2024	27/03/2024	27/03/2024	02/04/2024	02/04/2024	03/04/2024	04/04/2024	09/04/2024	09/04/2024	11/04/2024
D52	17/04/2024	18/04/2024	02/05/2024	03/05/2024	06/05/2024	06/05/2024	07/05/2024	08/05/2024	14/05/2024	14/05/2024	16/05/2024

	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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
D53	15/05/2024	16/05/2024	29/05/2024	31/05/2024	03/06/2024	03/06/2024	04/06/2024	06/06/2024	11/06/2024	11/06/2024	13/06/2024
D54	12/06/2024	13/06/2024	26/06/2024	28/06/2024	01/07/2024	01/07/2024	02/07/2024	04/07/2024	09/07/2024	09/07/2024	11/07/2024
D55											
D56	07/08/2024	08/08/2024	21/08/2024	23/08/2024	26/08/2024	26/08/2024	27/08/2024	29/08/2024	03/09/2024	03/09/2024	05/09/2024
D57	04/09/2024	05/09/2024	18/09/2024	20/09/2024	23/09/2024	23/09/2024	24/09/2024	26/09/2024	01/10/2024	01/10/2024	03/10/2024
D58	02/10/2024	03/10/2024	16/10/2024	18/10/2024	21/10/2024	21/10/2024	22/10/2024	24/10/2024	29/10/2024	29/10/2024	31/10/2024
D59	30/10/2024	31/10/2024	13/11/2024	15/11/2024	18/11/2024	18/11/2024	19/11/2024	21/11/2024	26/11/2024	26/11/2024	28/11/2024

(-) 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 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 timetable<sup>1</sup>

	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	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
E2	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
E3	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
E4	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
E5	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
E6	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
E7											
E8	12/08/2020	13/08/2020	19/08/2020	19/08/2020	24/08/2020	24/08/2020	27/08/2020	27/08/2020	02/09/2020	02/09/2020	04/09/2020
E9	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
E10	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
E11	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
E12	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
E13	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
E14	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
E15	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
E16	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
E17	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
E18	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
E19											
E20	11/08/2021	12/08/2021	18/08/2021	18/08/2021	23/08/2021	23/08/2021	26/08/2021	26/08/2021	01/09/2021	01/09/2021	02/09/2021
E21	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
E22	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
E23	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
E24	13/12/2021	15/12/2021	03/01/2022	03/01/2022	05/01/2022	05/01/2022	06/01/2022	06/01/2022	11/01/2022	11/01/2022	13/01/2022
E25	18/01/2022	19/01/2022	26/01/2022	26/01/2022	31/01/2022	31/01/2022	03/02/2022	03/02/2022	08/02/2022	08/02/2022	10/02/2022

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

	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 (***) (~)	PRAC Outcome	Start of CHMP written procedure (#)	Request for Supplementary Information (RSI) or Opinion
E53	21/05/2024	22/05/2024	29/05/2024	29/05/2024	03/06/2024	03/06/2024	06/06/2024	06/06/2024	11/06/2024	11/06/2024	13/06/2024
E54	18/06/2024	19/06/2024	26/06/2024	26/06/2024	01/07/2024	01/07/2024	04/07/2024	04/07/2024	09/07/2024	09/07/2024	11/07/2024
E55											
E56	05/08/2024	07/08/2024	21/08/2024	21/08/2024	26/08/2024	26/08/2024	29/08/2024	29/08/2024	03/09/2024	03/09/2024	05/09/2024
E57	10/09/2024	11/09/2024	18/09/2024	18/09/2024	23/09/2024	23/09/2024	26/09/2024	26/09/2024	01/10/2024	01/10/2024	03/10/2024
E58	08/10/2024	09/10/2024	16/10/2024	16/10/2024	21/10/2024	21/10/2024	24/10/2024	24/10/2024	29/10/2024	29/10/2024	31/10/2024
E59	05/11/2024	06/11/2024	13/11/2024	13/11/2024	18/11/2024	18/11/2024	21/11/2024	21/11/2024	26/11/2024	26/11/2024	28/11/2024

(-) 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 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.