



27 August 2024  
EMA/577385/2016 Rev.10  
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 timetable<sup>7</sup>

	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	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
A2	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
A3	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
A4	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
A5	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
A6	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
A7	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
A8										
A9	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
A10	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
A11	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
A12	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
A13	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
A14	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
A15	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
A16	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
A17	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
A18	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
A19	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
A20										
A21	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
A22	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
A23	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
A24	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
A25	16/10/2024	02/11/2024	20/12/2024	03/01/2025	08/01/2025	09/01/2025	16/01/2025	20/01/2025	23/01/2025	30/01/2025

	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
A26	13/11/2024	30/11/2024	24/01/2025	31/01/2025	05/02/2025	06/02/2025	13/02/2025	17/02/2025	20/02/2025	27/02/2025
A27	04/12/2024	28/12/2024	21/02/2025	28/02/2025	05/03/2025	06/03/2025	13/03/2025	17/03/2025	20/03/2025	27/03/2025
A28	09/01/2025	26/01/2025	21/03/2025	28/03/2025	02/04/2025	03/04/2025	10/04/2025	14/04/2025	16/04/2025	25/04/2025
A29	05/02/2025	22/02/2025	16/04/2025	25/04/2025	30/04/2025	02/05/2025	08/05/2025	12/05/2025	15/05/2025	22/05/2025
A30	05/03/2025	22/03/2025	16/05/2025	23/05/2025	27/05/2025	28/05/2025	05/06/2025	10/06/2025	12/06/2025	19/06/2025
A31	09/04/2025	26/04/2025	20/06/2025	27/06/2025	02/07/2025	03/07/2025	10/07/2025	14/07/2025	17/07/2025	24/07/2025
A32										
A33	04/06/2025	21/06/2025	14/08/2025	22/08/2025	27/08/2025	28/08/2025	04/09/2025	08/09/2025	11/09/2025	18/09/2025
A34	02/07/2025	19/07/2025	12/09/2025	19/09/2025	24/09/2025	25/09/2025	02/10/2025	06/10/2025	09/10/2025	16/10/2025
A35	30/07/2025	16/08/2025	10/10/2025	17/10/2025	22/10/2025	23/10/2025	30/10/2025	03/11/2025	06/11/2025	13/11/2025
A36	27/08/2025	13/09/2025	07/11/2025	14/11/2025	19/11/2025	20/11/2025	27/11/2025	01/12/2025	04/12/2025	11/12/2025
A37	15/10/2025	01/11/2025	23/12/2025	02/01/2026	07/01/2026	08/01/2026	15/01/2026	19/01/2026	22/01/2026	29/01/2026
A38	12/11/2025	29/11/2025	23/01/2026	30/01/2026	04/02/2026	05/02/2026	12/02/2026	16/02/2026	19/02/2026	26/02/2026
A39	03/12/2025	27/12/2025	20/02/2026	27/02/2026	04/03/2026	05/03/2026	12/03/2026	16/03/2026	19/03/2026	26/03/2026
A40	07/01/2026	24/01/2026	20/03/2026	27/03/2026	31/03/2026	01/04/2026	10/04/2026	13/04/2026	16/04/2026	23/04/2026
A41	04/02/2026	21/02/2026	17/04/2026	24/04/2026	29/04/2026	30/04/2026	07/05/2026	11/05/2026	13/05/2026	21/05/2026
A42	11/03/2026	28/03/2026	22/05/2026	29/05/2026	03/06/2026	04/06/2026	11/06/2026	15/06/2026	18/06/2026	25/06/2026
A43	08/04/2026	25/04/2026	19/06/2026	26/06/2026	01/07/2026	02/07/2026	09/07/2026	13/07/2026	16/07/2026	23/07/2026
A44										
A45	03/06/2026	20/06/2026	14/08/2026	21/08/2026	26/08/2026	27/08/2026	03/09/2026	07/09/2026	10/09/2026	17/09/2026
A46	01/07/2026	18/07/2026	11/09/2026	18/09/2026	23/09/2026	24/09/2026	01/10/2026	05/10/2026	08/10/2026	15/10/2026
A47	29/07/2026	15/08/2026	09/10/2026	16/10/2026	21/10/2026	22/10/2026	29/10/2026	03/11/2026	05/11/2026	12/11/2026
A48	26/08/2026	12/09/2026	06/11/2026	13/11/2026	18/11/2026	19/11/2026	26/11/2026	30/11/2026	03/12/2026	10/12/2026

(-) 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.

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
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(\*) 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. The Rapporteur AR and Co-Rapporteur assessment will be both made available to the applicant

## 60-day initial submission assessment timetable<sup>7</sup>

	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	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
B2	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
B3	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
B4	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
B5	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
B6	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
B7	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
B8											
B9	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
B10	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
B11	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
B12	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
B13	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
B14	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
B15	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
B16	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
B17	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
B18	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
B19	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
B20											
B21	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
B22	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
B23	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
B24	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
B25	15/11/2024	02/12/2024	06/01/2025	02/01/2025	06/01/2025	08/01/2025	09/01/2025	16/01/2025	20/01/2025	23/01/2025	30/01/2025

	Submission deadline (*)	Start date (^)	CHMP Rapporteur AR (if PRAC is not involved)	Steps only applicable in case of PRAC involvement					Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
				CHMP Rapporteur AR	PRAC Rapporteur AR	Comments from PRAC (**)	Updated PRAC Rapporteur AR (***)	PRAC outcome			
B26	29/11/2024	30/12/2024	03/02/2025	28/01/2025	31/01/2025	05/02/2025	06/02/2025	13/02/2025	17/02/2025	20/02/2025	27/02/2025
B27	10/01/2025	27/01/2025	03/03/2025	25/02/2025	28/02/2025	05/03/2025	06/03/2025	13/03/2025	17/03/2025	20/03/2025	27/03/2025
B28	07/02/2025	25/02/2025	31/03/2025	25/03/2025	28/03/2025	02/04/2025	03/04/2025	10/04/2025	14/04/2025	16/04/2025	25/04/2025
B29	07/03/2025	24/03/2025	28/04/2025	22/04/2025	25/04/2025	30/04/2025	02/05/2025	08/05/2025	12/05/2025	15/05/2025	22/05/2025
B30	04/04/2025	21/04/2025	26/05/2025	20/05/2025	23/05/2025	27/05/2025	28/05/2025	05/06/2025	10/06/2025	12/06/2025	19/06/2025
B31	08/05/2025	26/05/2025	30/06/2025	24/06/2025	27/06/2025	02/07/2025	03/07/2025	10/07/2025	14/07/2025	17/07/2025	24/07/2025
B32											
B33	04/07/2025	21/07/2025	25/08/2025	19/08/2025	22/08/2025	27/08/2025	28/08/2025	04/09/2025	08/09/2025	11/09/2025	18/09/2025
B34	01/08/2025	18/08/2025	22/09/2025	16/09/2025	19/09/2025	24/09/2025	25/09/2025	02/10/2025	06/10/2025	09/10/2025	16/10/2025
B35	29/08/2025	15/09/2025	20/10/2025	14/10/2025	17/10/2025	22/10/2025	23/10/2025	30/10/2025	03/11/2025	06/11/2025	13/11/2025
B36	26/09/2025	13/10/2025	17/11/2025	11/11/2025	14/11/2025	19/11/2025	20/11/2025	27/11/2025	01/12/2025	04/12/2025	11/12/2025
B37	14/11/2025	01/12/2025	05/01/2026	02/01/2026	05/01/2026	08/01/2026	09/01/2026	15/01/2026	19/01/2026	22/01/2026	29/01/2026
B38	28/11/2025	29/12/2025	02/02/2026	27/01/2026	30/01/2026	04/02/2026	05/02/2026	12/02/2026	16/02/2026	19/02/2026	26/02/2026
B39	09/01/2026	26/01/2026	02/03/2026	24/02/2026	27/02/2026	04/03/2026	05/03/2026	12/03/2026	16/03/2026	19/03/2026	26/03/2026
B40	06/02/2026	23/02/2026	30/03/2026	24/03/2026	27/03/2026	31/03/2026	01/04/2026	10/04/2026	13/04/2026	16/04/2026	23/04/2026
B41	06/03/2026	23/03/2026	28/04/2026	21/04/2026	24/04/2026	29/04/2026	30/04/2026	07/05/2026	11/05/2026	13/05/2026	21/05/2026
B42	10/04/2026	27/04/2026	01/06/2026	26/05/2026	29/05/2026	03/06/2026	04/06/2026	11/06/2026	15/06/2026	18/06/2026	25/06/2026
B43	08/05/2026	25/05/2026	29/06/2026	23/06/2026	26/06/2026	01/07/2026	02/07/2026	09/07/2026	13/07/2026	16/07/2026	23/07/2026
B44											
B45	03/07/2026	20/07/2026	24/08/2026	18/08/2026	21/08/2026	26/08/2026	27/08/2026	03/09/2026	07/09/2026	10/09/2026	17/09/2026
B46	31/07/2026	17/08/2026	21/09/2026	15/09/2026	18/09/2026	23/09/2026	24/09/2026	01/10/2026	05/10/2026	08/10/2026	15/10/2026
B47	28/08/2026	14/09/2026	19/10/2026	13/10/2026	16/10/2026	21/10/2026	22/10/2026	29/10/2026	03/11/2026	05/11/2026	12/11/2026
B48	25/09/2026	12/10/2026	16/11/2026	10/11/2026	13/11/2026	18/11/2026	19/11/2026	26/11/2026	30/11/2026	03/12/2026	10/12/2026

(↯) 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.

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			

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

	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	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
C2	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
C3	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
C4	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
C5	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
C6	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
C7	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
C8										
C9	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
C10	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
C11	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
C12	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
C13	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
C14	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
C15	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
C16	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
C17	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
C18	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
C19	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
C20										
C21	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
C22	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
C23	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
C24	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
C25	02/12/2024	01/01/2025	06/01/2025	08/01/2025	09/01/2025	15/01/2025	16/01/2025	20/01/2025	23/01/2025	30/01/2025



	Submission deadline (*)	Start date (^)	PRAC Rapporteur AR (~)	Comments from PRAC (**)(~)	Updated PRAC Rapporteur AR (***)(~)	CHMP Rapporteur AR	PRAC outcome (~)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	Request for Supplementary Information (RSI) or Opinion
C26	17/01/2025	29/01/2025	03/02/2025	05/02/2025	06/02/2025	12/02/2025	13/02/2025	17/02/2025	20/02/2025	27/02/2025
C27	14/02/2025	26/02/2025	03/03/2025	05/03/2025	06/03/2025	12/03/2025	13/03/2025	17/03/2025	20/03/2025	27/03/2025
C28	14/03/2025	27/03/2025	31/03/2025	02/04/2025	03/04/2025	09/04/2025	10/04/2025	14/04/2025	16/04/2025	25/04/2025
C29	11/04/2025	23/04/2025	28/04/2025	30/04/2025	02/05/2025	07/05/2025	08/05/2025	12/05/2025	15/05/2025	22/05/2025
C30	08/05/2025	21/05/2025	26/05/2025	28/05/2025	02/06/2025	04/06/2025	05/06/2025	10/06/2025	12/06/2025	19/06/2025
C31	13/06/2025	25/06/2025	30/06/2025	02/07/2025	03/07/2025	09/07/2025	10/07/2025	14/07/2025	17/07/2025	24/07/2025
C32										
C33	08/08/2025	20/08/2025	25/08/2025	27/08/2025	28/08/2025	03/09/2025	04/09/2025	08/09/2025	11/09/2025	18/09/2025
C34	05/09/2025	17/09/2025	22/09/2025	24/09/2025	25/09/2025	01/10/2025	02/10/2025	06/10/2025	09/10/2025	16/10/2025
C35	03/10/2025	15/10/2025	20/10/2025	22/10/2025	23/10/2025	29/10/2025	30/10/2025	03/11/2025	06/11/2025	13/11/2025
C36	30/10/2025	12/11/2025	17/11/2025	19/11/2025	20/11/2025	26/11/2025	27/11/2025	01/12/2025	04/12/2025	11/12/2025
C37	01/12/2025	31/12/2025	05/01/2026	07/01/2026	08/01/2026	14/01/2026	15/01/2026	19/01/2026	22/01/2026	29/01/2026
C38	16/01/2026	28/01/2026	02/02/2026	04/02/2026	05/02/2026	11/02/2026	12/02/2026	16/02/2026	19/02/2026	26/02/2026
C39	13/02/2026	25/02/2026	02/03/2026	04/03/2026	05/03/2026	11/03/2026	12/03/2026	16/03/2026	19/03/2026	26/03/2026
C40	13/03/2026	25/03/2026	30/03/2026	01/04/2026	07/04/2026	08/04/2026	10/04/2026	13/04/2026	16/04/2026	23/04/2026
C41	10/04/2026	22/04/2026	28/04/2026	29/04/2026	30/04/2026	06/05/2026	07/05/2026	11/05/2026	13/05/2026	21/05/2026
C42	13/05/2026	27/05/2026	01/06/2026	03/06/2026	04/06/2026	10/06/2026	11/06/2026	15/06/2026	18/06/2026	25/06/2026
C43	12/06/2026	24/06/2026	29/06/2026	01/07/2026	02/07/2026	08/07/2026	09/07/2026	13/07/2026	16/07/2026	23/07/2026
C44										
C45	07/08/2026	19/08/2026	24/08/2026	26/08/2026	27/08/2026	02/09/2026	03/09/2026	07/09/2026	10/09/2026	17/09/2026
C46	04/09/2026	16/09/2026	21/09/2026	23/09/2026	24/09/2026	30/09/2026	01/10/2026	05/10/2026	08/10/2026	15/10/2026
C47	02/10/2026	14/10/2026	19/10/2026	21/10/2026	22/10/2026	28/10/2026	29/10/2026	03/11/2026	05/11/2026	12/11/2026
C48	30/10/2026	11/11/2026	16/11/2026	18/11/2026	19/11/2026	25/11/2026	26/11/2026	30/11/2026	03/12/2026	10/12/2026

(~) 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.

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

	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	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
D2	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
D3	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
D4	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
D5	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
D6	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
D7	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
D8											
D9	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
D10	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
D11	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
D12	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
D13	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
D14	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
D15	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
D16	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
D17	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
D18	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
D19	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
D20											
D21	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
D22	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
D23	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
D24	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
D25	29/11/2024	02/12/2024	06/01/2025	02/01/2025	06/01/2025	08/01/2025	09/01/2025	16/01/2025	20/01/2025	23/01/2025	30/01/2025

	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			
D26	20/12/2024	30/12/2024	03/02/2025	28/01/2025	31/01/2025	05/02/2025	06/02/2025	13/02/2025	17/02/2025	20/02/2025	27/02/2025
D27	24/01/2025	27/01/2025	03/03/2025	25/02/2025	28/02/2025	05/03/2025	06/03/2025	13/03/2025	17/03/2025	20/03/2025	27/03/2025
D28	24/02/2025	25/02/2025	31/03/2025	25/03/2025	28/03/2025	02/04/2025	03/04/2025	10/04/2025	14/04/2025	16/04/2025	25/04/2025
D29	21/03/2025	24/03/2025	28/04/2025	22/04/2025	25/04/2025	30/04/2025	02/05/2025	08/05/2025	12/05/2025	15/05/2025	22/05/2025
D30	16/04/2025	21/04/2025	26/05/2025	20/05/2025	23/05/2025	27/05/2025	28/05/2025	05/06/2025	10/06/2025	12/06/2025	19/06/2025
D31	23/05/2025	26/05/2025	30/06/2025	24/06/2025	27/06/2025	02/07/2025	03/07/2025	10/07/2025	14/07/2025	17/07/2025	24/07/2025
D32											
D33	18/07/2025	21/07/2025	25/08/2025	19/08/2025	22/08/2025	27/08/2025	28/08/2025	04/09/2025	08/09/2025	11/09/2025	18/09/2025
D34	14/08/2025	18/08/2025	22/09/2025	16/09/2025	19/09/2025	24/09/2025	25/09/2025	02/10/2025	06/10/2025	09/10/2025	16/10/2025
D35	12/09/2025	15/09/2025	20/10/2025	14/10/2025	17/10/2025	22/10/2025	23/10/2025	30/10/2025	03/11/2025	06/11/2025	13/11/2025
D36	10/10/2025	13/10/2025	17/11/2025	11/11/2025	14/11/2025	19/11/2025	20/11/2025	27/11/2025	01/12/2025	04/12/2025	11/12/2025
D37	28/11/2025	01/12/2025	05/01/2026	02/01/2026	05/01/2026	08/01/2026	09/01/2026	15/01/2026	19/01/2026	22/01/2026	29/01/2026
D38	22/12/2025	29/12/2025	02/02/2026	27/01/2026	30/01/2026	04/02/2026	05/02/2026	12/02/2026	16/02/2026	19/02/2026	26/02/2026
D39	23/01/2026	26/01/2026	02/03/2026	24/02/2026	27/02/2026	04/03/2026	05/03/2026	12/03/2026	16/03/2026	19/03/2026	26/03/2026
D40	20/02/2026	23/02/2026	30/03/2026	24/03/2026	27/03/2026	31/03/2026	01/04/2026	10/04/2026	13/04/2026	16/04/2026	23/04/2026
D41	20/03/2026	23/03/2026	28/04/2026	21/04/2026	24/04/2026	29/04/2026	30/04/2026	07/05/2026	11/05/2026	13/05/2026	21/05/2026
D42	24/04/2026	27/04/2026	01/06/2026	26/05/2026	29/05/2026	03/06/2026	04/06/2026	11/06/2026	15/06/2026	18/06/2026	25/06/2026
D43	22/05/2026	25/05/2026	29/06/2026	23/06/2026	26/06/2026	01/07/2026	02/07/2026	09/07/2026	13/07/2026	16/07/2026	23/07/2026
D44											
D45	17/07/2026	20/07/2026	24/08/2026	18/08/2026	21/08/2026	26/08/2026	27/08/2026	03/09/2026	07/09/2026	10/09/2026	17/09/2026
D46	14/08/2026	17/08/2026	21/09/2026	15/09/2026	18/09/2026	23/09/2026	24/09/2026	01/10/2026	05/10/2026	08/10/2026	15/10/2026
D47	11/09/2026	14/09/2026	19/10/2026	13/10/2026	16/10/2026	21/10/2026	22/10/2026	29/10/2026	03/11/2026	05/11/2026	12/11/2026
D48	09/10/2026	12/10/2026	16/11/2026	10/11/2026	13/11/2026	18/11/2026	19/11/2026	26/11/2026	30/11/2026	03/12/2026	10/12/2026

(–) 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.

	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			

(\*\*\*) 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 timetable<sup>7</sup>

	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	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
E2	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
E3	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
E4	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
E5	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
E6	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
E7	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
E8										
E9	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
E10	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
E11	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
E12	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
E13	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
E14	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
E15	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
E16	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
E17	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
E18	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
E19	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
E20										
E21	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
E22	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
E23	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
E24	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
E25	20/12/2024	01/01/2025	06/01/2025	08/01/2025	09/01/2025	15/01/2025	16/01/2025	20/01/2025	23/01/2025	30/01/2025
E26	28/01/2025	29/01/2025	03/02/2025	05/02/2025	06/02/2025	12/02/2025	13/02/2025	17/02/2025	20/02/2025	27/02/2025
E27	25/02/2025	26/02/2025	03/03/2025	05/03/2025	06/03/2025	12/03/2025	13/03/2025	17/03/2025	20/03/2025	27/03/2025

	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
E28	26/03/2025	27/03/2025	31/03/2025	02/04/2025	03/04/2025	09/04/2025	10/04/2025	14/04/2025	16/04/2025	25/04/2025
E29	22/04/2025	23/04/2025	28/04/2025	30/04/2025	02/05/2025	07/05/2025	08/05/2025	12/05/2025	15/05/2025	22/05/2025
E30	20/05/2025	21/05/2025	26/05/2025	28/05/2025	02/06/2025	04/06/2025	05/06/2025	10/06/2025	12/06/2025	19/06/2025
E31	24/06/2025	25/06/2025	30/06/2025	02/07/2025	03/07/2025	09/07/2025	10/07/2025	14/07/2025	17/07/2025	24/07/2025
E32										
E33	19/08/2025	20/08/2025	25/08/2025	27/08/2025	28/08/2025	03/09/2025	04/09/2025	08/09/2025	11/09/2025	18/09/2025
E34	16/09/2025	17/09/2025	22/09/2025	24/09/2025	25/09/2025	01/10/2025	02/10/2025	06/10/2025	09/10/2025	16/10/2025
E35	14/10/2025	15/10/2025	20/10/2025	22/10/2025	23/10/2025	29/10/2025	30/10/2025	03/11/2025	06/11/2025	13/11/2025
E36	11/11/2025	12/11/2025	17/11/2025	19/11/2025	20/11/2025	26/11/2025	27/11/2025	01/12/2025	04/12/2025	11/12/2025
E37	22/12/2025	31/12/2025	05/01/2026	07/01/2026	08/01/2026	14/01/2026	15/01/2026	19/01/2026	22/01/2026	29/01/2026
E38	27/01/2026	28/01/2026	02/02/2026	04/02/2026	05/02/2026	11/02/2026	12/02/2026	16/02/2026	19/02/2026	26/02/2026
E39	24/02/2026	25/02/2026	02/03/2026	04/03/2026	05/03/2026	11/03/2026	12/03/2026	16/03/2026	19/03/2026	26/03/2026
E40	24/03/2026	25/03/2026	30/03/2026	01/04/2026	07/04/2026	08/04/2026	10/04/2026	13/04/2026	16/04/2026	23/04/2026
E41	21/04/2026	22/04/2026	28/04/2026	29/04/2026	30/04/2026	06/05/2026	07/05/2026	11/05/2026	13/05/2026	21/05/2026
E42	26/05/2026	27/05/2026	01/06/2026	03/06/2026	04/06/2026	10/06/2026	11/06/2026	15/06/2026	18/06/2026	25/06/2026
E43	23/06/2026	24/06/2026	29/06/2026	01/07/2026	02/07/2026	08/07/2026	09/07/2026	13/07/2026	16/07/2026	23/07/2026
E44										
E45	18/08/2026	19/08/2026	24/08/2026	26/08/2026	27/08/2026	02/09/2026	03/09/2026	07/09/2026	10/09/2026	17/09/2026
E46	15/09/2026	16/09/2026	21/09/2026	23/09/2026	24/09/2026	30/09/2026	01/10/2026	05/10/2026	08/10/2026	15/10/2026
E47	13/10/2026	14/10/2026	19/10/2026	21/10/2026	22/10/2026	28/10/2026	29/10/2026	03/11/2026	05/11/2026	12/11/2026
E48	10/11/2026	11/11/2026	16/11/2026	18/11/2026	19/11/2026	25/11/2026	26/11/2026	30/11/2026	03/12/2026	10/12/2026

(→) 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 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 (***)	Request for Supplementary Information (RSI) or Opinion
F1	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
F2	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
F3	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
F4	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
F5	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
F6	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
F7	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
F8									
F9	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
F10	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
F11	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
F12	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
F13	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
F14	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
F15	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
F16	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
F17	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
F18	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
F19	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
F20									
F21	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
F22	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
F23	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
F24	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
F25	20/12/2024	01/01/2025	15/01/2025	15/01/2025	20/01/2025	20/01/2025	23/01/2025	23/01/2025	30/01/2025
F26	04/02/2025	05/02/2025	12/02/2025	12/02/2025	17/02/2025	17/02/2025	20/02/2025	20/02/2025	27/02/2025
F27	04/03/2025	05/03/2025	12/03/2025	12/03/2025	17/03/2025	17/03/2025	20/03/2025	20/03/2025	27/03/2025



	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
F28	02/04/2025	03/04/2025	09/04/2025	09/04/2025	14/04/2025	14/04/2025	16/04/2025	16/04/2025	25/04/2025
F29	29/04/2025	30/04/2025	07/05/2025	07/05/2025	12/05/2025	12/05/2025	15/05/2025	15/05/2025	22/05/2025
F30	27/05/2025	28/05/2025	04/06/2025	04/06/2025	10/06/2025	10/06/2025	12/06/2025	12/06/2025	19/06/2025
F31	27/06/2025	30/06/2025	09/07/2025	09/07/2025	14/07/2025	14/07/2025	17/07/2025	17/07/2025	24/07/2025
F32									
F33	19/08/2025	20/08/2025	03/09/2025	03/09/2025	08/09/2025	08/09/2025	11/09/2025	11/09/2025	18/09/2025
F34	23/09/2025	24/09/2025	01/10/2025	01/10/2025	06/10/2025	06/10/2025	09/10/2025	09/10/2025	16/10/2025
F35	21/10/2025	22/10/2025	29/10/2025	29/10/2025	03/11/2025	03/11/2025	06/11/2025	06/11/2025	13/11/2025
F36	18/11/2025	19/11/2025	26/11/2025	26/11/2025	01/12/2025	01/12/2025	04/12/2025	04/12/2025	11/12/2025
F37	20/12/2025	31/12/2025	14/01/2026	14/01/2026	19/01/2026	19/01/2026	22/01/2026	22/01/2026	29/01/2026
F38	03/02/2026	04/02/2026	11/02/2026	11/02/2026	16/02/2026	16/02/2026	19/02/2026	19/02/2026	26/02/2026
F39	03/03/2026	04/03/2026	11/03/2026	11/03/2026	16/03/2026	16/03/2026	19/03/2026	19/03/2026	26/03/2026
F40	31/03/2026	01/04/2026	08/04/2026	08/04/2026	13/04/2026	13/04/2026	16/04/2026	16/04/2026	23/04/2026
F41	28/04/2026	29/04/2026	06/05/2026	06/05/2026	11/05/2026	11/05/2026	13/05/2026	13/05/2026	21/05/2026
F42	29/05/2026	01/06/2026	10/06/2026	10/06/2026	15/06/2026	15/06/2026	18/06/2026	18/06/2026	25/06/2026
F43	30/06/2026	01/07/2026	08/07/2026	08/07/2026	13/07/2026	13/07/2026	16/07/2026	16/07/2026	23/07/2026
F44									
F45	17/08/2026	19/08/2026	02/09/2026	02/09/2026	07/09/2026	07/09/2026	10/09/2026	10/09/2026	17/09/2026
F46	22/09/2026	23/09/2026	30/09/2026	30/09/2026	05/10/2026	05/10/2026	08/10/2026	08/10/2026	15/10/2026
F47	20/10/2026	21/10/2026	28/10/2026	28/10/2026	03/11/2026	03/11/2026	05/11/2026	05/11/2026	12/11/2026
F48	17/11/2026	18/11/2026	25/11/2026	25/11/2026	30/11/2026	30/11/2026	03/12/2026	03/12/2026	10/12/2026

(-) 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.