



21 December 2020  
EMA/824995/2015 Rev.4  
Human Medicines

The timetables in this document may be subject to revision

## Extension application\* assessment timetables - ATMP

[Assessment of initial submission \(120-day timetable\)](#)

[Assessment of responses to List of Questions \(60-day timetable after clock-stop for submission of responses\)](#)

[Assessment of responses to List of Outstanding Issues \(30-day timetable after clock-stop for responses\)](#)

[Assessment of responses to List of Outstanding Issues \(30-day timetable after immediate responses\)](#)

\*These are also known as Annex I (of Regulation EC No 1234/2008) applications.

## Assessment of initial submission (120-day timetable)

	Deadline for Submission (*)	Start date (^)	CAT (Co) Rapporteur ARs (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***)	PRAC outcome (~)	Draft LoQ (***)	CAT List of Questions (LoQ) or Opinion	CHMP Opinion (#)
A1	13/01/2020	28/01/2020	20/04/2020	28/04/2020	04/05/2020	07/05/2020	08/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
A2	10/02/2020	27/02/2020	18/05/2020	26/05/2020	02/06/2020	04/06/2020	05/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
A3	09/03/2020	26/03/2020	15/06/2020	23/06/2020	29/06/2020	02/07/2020	03/07/2020	09/07/2020	13/07/2020	17/07/2020	23/07/2020
A4											
A5	04/05/2020	21/05/2020	10/08/2020	18/08/2020	24/08/2020	27/08/2020	28/08/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
A6	01/06/2020	18/06/2020	07/09/2020	15/09/2020	21/09/2020	24/09/2020	25/09/2020	01/10/2020	05/10/2020	09/10/2020	15/10/2020
A7	29/06/2020	16/07/2020	05/10/2020	13/10/2020	19/10/2020	22/10/2020	23/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020
A8	27/07/2020	13/08/2020	03/11/2020	10/11/2020	16/11/2020	19/11/2020	20/11/2020	26/11/2020	30/11/2020	04/12/2020	10/12/2020
A9	14/09/2020	01/10/2020	21/12/2020	04/01/2021	06/01/2021	07/01/2021	08/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
A10	12/10/2020	29/10/2020	18/01/2021	26/01/2021	01/02/2021	04/02/2021	05/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
A11	09/11/2020	26/11/2020	15/02/2021	23/02/2021	01/03/2021	04/03/2021	05/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
A12	23/11/2020	24/12/2020	15/03/2021	23/03/2021	26/03/2021	30/03/2021	31/03/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
A13	04/01/2021	19/01/2021	12/04/2021	20/04/2021	26/04/2021	29/04/2021	30/04/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
A14	08/02/2021	25/02/2021	17/05/2021	25/05/2021	31/05/2021	03/06/2021	04/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
A15	08/03/2021	25/03/2021	14/06/2021	22/06/2021	28/06/2021	01/07/2021	02/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
A16											
A17	30/04/2021	20/05/2021	09/08/2021	17/08/2021	23/08/2021	26/08/2021	27/08/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
A18	31/05/2021	17/06/2021	06/09/2021	14/09/2021	20/09/2021	23/09/2021	24/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
A19	28/06/2021	15/07/2021	04/10/2021	12/10/2021	18/10/2021	21/10/2021	22/10/2021	28/10/2021	29/10/2021	05/11/2021	11/11/2021
A20	02/08/2021	19/08/2021	08/11/2021	16/11/2021	22/11/2021	25/11/2021	26/11/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
A21	13/09/2021	30/09/2021	20/12/2021	03/01/2022	05/01/2022	06/01/2022	07/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
A22	11/10/2021	28/10/2021	17/01/2022	25/01/2022	31/01/2022	03/02/2022	04/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022
A23	08/11/2021	25/11/2021	14/02/2022	22/02/2022	28/02/2022	03/03/2022	04/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
A24	29/11/2021	21/12/2021	14/03/2022	22/03/2022	28/03/2022	31/03/2022	01/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
A25	03/01/2022	20/01/2022	11/04/2022	19/04/2022	25/04/2022	28/04/2022	29/04/2022	05/05/2022	10/05/2022	13/05/2022	19/05/2022

	Deadline for Submission (*)	Start date (^)	CAT (Co) Rapporteur ARs (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***)	PRAC outcome (~)	Draft LoQ (***)	CAT List of Questions (LoQ) or Opinion	CHMP Opinion (#)
A26	07/02/2022	24/02/2022	16/05/2022	24/05/2022	30/05/2022	02/06/2022	03/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
A27	07/03/2022	24/03/2022	13/06/2022	21/06/2022	27/06/2022	30/06/2022	01/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
A28											
A29	02/05/2022	19/05/2022	08/08/2022	16/08/2022	22/08/2022	25/08/2022	26/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
A30	30/05/2022	16/06/2022	05/09/2022	13/09/2022	19/09/2022	22/09/2022	23/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
A31	27/06/2022	14/07/2022	03/10/2022	11/10/2022	17/10/2022	20/10/2022	21/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
A32	01/08/2022	18/08/2022	07/11/2022	15/11/2022	21/11/2022	24/11/2022	25/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
A33	12/09/2022	29/09/2022	19/12/2022	03/01/2023	04/01/2023	05/01/2023	06/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
A34	10/10/2022	27/10/2022	16/01/2023	24/01/2023	30/01/2023	02/02/2023	03/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
A35	14/11/2022	01/12/2022	20/02/2023	28/02/2023	06/03/2023	09/03/2023	10/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
A36	28/11/2022	29/12/2022	20/03/2023	28/03/2023	03/04/2023	05/04/2023	05/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
A37	05/01/2023	24/01/2023	17/04/2023	25/04/2023	02/05/2023	04/05/2023	05/05/2023	12/05/2023	12/05/2023	17/05/2023	25/05/2023
A38	06/02/2023	23/02/2023	15/05/2023	23/05/2023	30/05/2023	01/06/2023	02/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
A39	06/03/2023	23/03/2023	12/06/2023	20/06/2023	26/06/2023	29/06/2023	30/06/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
A40											
A41	26/04/2023	18/05/2023	07/08/2023	16/08/2023	21/08/2023	24/08/2023	25/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
A42	26/05/2023	15/06/2023	04/09/2023	12/09/2023	18/09/2023	21/09/2023	22/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
A43	21/06/2023	10/07/2023	02/10/2023	10/10/2023	16/10/2023	19/10/2023	20/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
A44	31/07/2023	17/08/2023	06/11/2023	14/11/2023	20/11/2023	23/11/2023	24/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
A45	11/09/2023	28/09/2023	18/12/2023	03/01/2024	04/01/2024	05/01/2024	05/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
A46	09/10/2023	26/10/2023	15/01/2024	23/01/2024	29/01/2024	01/02/2024	02/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
A47	06/11/2023	23/11/2023	12/02/2024	20/02/2024	26/02/2024	29/02/2024	01/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
A48	27/11/2023	28/12/2023	18/03/2024	26/03/2024	02/04/2024	04/04/2024	05/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024
A49	15/01/2024	01/02/2024	22/04/2024	30/04/2024	06/05/2024	08/05/2024	08/05/2024	16/05/2024	21/05/2024	24/05/2024	30/05/2024
A50	12/02/2024	29/02/2024	21/05/2024	28/05/2024	03/06/2024	06/06/2024	07/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
A51	11/03/2024	28/03/2024	17/06/2024	25/06/2024	01/07/2024	04/07/2024	05/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
A52											

	Deadline for Submission (*)	Start date (^)	CAT (Co) Rapporteur ARs (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***)	PRAC outcome (~)	Draft LoQ (***)	CAT List of Questions (LoQ) or Opinion	CHMP Opinion (#)
A53	30/04/2024	23/05/2024	12/08/2024	20/08/2024	26/08/2024	29/08/2024	30/08/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
A54	03/06/2024	20/06/2024	09/09/2024	17/09/2024	23/09/2024	26/09/2024	27/09/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
A55	01/07/2024	18/07/2024	07/10/2024	15/10/2024	21/10/2024	24/10/2024	25/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
A56	29/07/2024	15/08/2024	04/11/2024	12/11/2024	18/11/2024	21/11/2024	22/11/2024	28/11/2024	02/12/2024	06/12/2024	12/12/2024

(\*) 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 submission date and start date is thirteen EMA working days. For further information about the dates on which the Agency will be closed during the current year, please refer to the business hours and holidays page on the website.

(\*\*) The Co-Rapporteur is involved only in case the extension application is submitted in support of an extension of indication.

(~) Step applicable only if RMP is submitted.

(\*\*\*) Comments from CAT, CHMP and PRAC members are not made available to MAHs.

(#) Step applicable only in case of CAT Opinion (not applicable in case a List of Questions is adopted by the CAT).

## Assessment of responses to List of Questions (LOQ)

60-day timetable after clock-stop for submission of responses

	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (^) (**)	CAT Rapporteur(s) Joint) AR (~) (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***) (***)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT List of Outstanding Issues (LoOI) or Opinion	CHMP Opinion (#)
B1	23/12/2019	24/12/2019	28/01/2020	24/01/2020	30/01/2020	04/02/2020	06/02/2020	11/02/2020	13/02/2020	17/02/2020	21/02/2020	27/02/2020
B2	20/01/2020	21/01/2020	25/02/2020	21/02/2020	27/02/2020	03/03/2020	05/03/2020	10/03/2020	12/03/2020	16/03/2020	20/03/2020	26/03/2020
B3	24/02/2020	25/02/2020	31/03/2020	27/03/2020	02/04/2020	07/04/2020	08/04/2020	15/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
B4	20/03/2020	22/03/2020	27/04/2020	24/04/2020	30/04/2020	05/05/2020	07/05/2020	12/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
B5	20/04/2020	21/04/2020	26/05/2020	20/05/2020	28/05/2020	02/06/2020	04/06/2020	09/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
B6	18/05/2020	19/05/2020	23/06/2020	19/06/2020	25/06/2020	30/06/2020	02/07/2020	07/07/2020	09/07/2020	13/07/2020	17/07/2020	23/07/2020
B7												
B8	13/07/2020	14/07/2020	18/08/2020	14/08/2020	20/08/2020	25/08/2020	27/08/2020	02/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
B9	10/08/2020	11/08/2020	15/09/2020	11/09/2020	17/09/2020	22/09/2020	24/09/2020	29/09/2020	01/10/2020	05/10/2020	09/10/2020	15/10/2020
B10	07/09/2020	08/09/2020	13/10/2020	09/10/2020	15/10/2020	20/10/2020	22/10/2020	27/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020
B11	05/10/2020	06/10/2020	10/11/2020	06/11/2020	12/11/2020	17/11/2020	19/11/2020	24/11/2020	26/11/2020	30/11/2020	04/12/2020	10/12/2020
B12	23/11/2020	24/11/2020	04/01/2021	22/12/2020	04/01/2021	05/01/2021	07/01/2021	12/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
B13	21/12/2020	22/12/2020	26/01/2021	22/01/2021	28/01/2021	02/02/2021	04/02/2021	09/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
B14	18/01/2021	19/01/2021	23/02/2021	19/02/2021	25/02/2021	02/03/2021	04/03/2021	09/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
B15	15/02/2021	16/02/2021	23/03/2021	19/03/2021	25/03/2021	30/03/2021	31/03/2021	07/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
B16	12/03/2021	14/03/2021	19/04/2021	16/04/2021	22/04/2021	27/04/2021	29/04/2021	04/05/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
B17	19/04/2021	20/04/2021	25/05/2021	21/05/2021	27/05/2021	01/06/2021	03/06/2021	08/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
B18	17/05/2021	18/05/2021	22/06/2021	18/06/2021	24/06/2021	29/06/2021	01/07/2021	06/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
B19												
B20	12/07/2021	13/07/2021	17/08/2021	13/08/2021	19/08/2021	24/08/2021	26/08/2021	01/09/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
B21	09/08/2021	10/08/2021	14/09/2021	10/09/2021	16/09/2021	21/09/2021	23/09/2021	28/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
B22	06/09/2021	07/09/2021	12/10/2021	08/10/2021	14/10/2021	19/10/2021	21/10/2021	26/10/2021	28/10/2021	29/10/2021	05/11/2021	11/11/2021
B23	11/10/2021	12/10/2021	16/11/2021	12/11/2021	18/11/2021	23/11/2021	25/11/2021	30/11/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
B24	22/11/2021	23/11/2021	22/12/2021	21/12/2021	03/01/2022	05/01/2022	06/01/2022	11/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
B25	20/12/2021	21/12/2021	25/01/2022	21/01/2022	27/01/2022	01/02/2022	03/02/2022	08/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022

	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (^) (**)	CAT Rapporteur(s) Joint) AR (~) (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT List of Outstanding Issues (LoOI) or Opinion	CHMP Opinion (#)
B26	17/01/2022	18/01/2022	22/02/2022	18/02/2022	24/02/2022	01/03/2022	03/03/2022	08/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
B27	11/02/2022	13/02/2022	22/03/2022	18/03/2022	24/03/2022	29/03/2022	31/03/2022	05/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
B28	14/03/2022	15/03/2022	19/04/2022	13/04/2022	21/04/2022	26/04/2022	28/04/2022	03/05/2022	05/05/2022	06/05/2022	13/05/2022	19/05/2022
B29	13/04/2022	19/04/2022	24/05/2022	20/05/2022	25/05/2022	31/05/2022	02/06/2022	07/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
B30	16/05/2022	17/05/2022	21/06/2022	17/06/2022	23/06/2022	28/06/2022	30/06/2022	05/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
B31												
B32	11/07/2022	12/07/2022	16/08/2022	12/08/2022	18/08/2022	23/08/2022	25/08/2022	30/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
B33	08/08/2022	09/08/2022	13/09/2022	09/09/2022	15/09/2022	20/09/2022	22/09/2022	27/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
B34	05/09/2022	06/09/2022	11/10/2022	07/10/2022	13/10/2022	18/10/2022	20/10/2022	25/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
B35	10/10/2022	11/10/2022	15/11/2022	11/11/2022	17/11/2022	22/11/2022	24/11/2022	29/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
B36	21/11/2022	22/11/2022	22/12/2022	22/12/2022	03/01/2023	04/01/2023	05/01/2023	10/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
B37	19/12/2022	20/12/2022	24/01/2023	20/01/2023	26/01/2023	31/01/2023	02/02/2023	07/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
B38	23/01/2023	24/01/2023	28/02/2023	24/02/2023	02/03/2023	07/03/2023	09/03/2023	14/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
B39	20/02/2023	21/02/2023	28/03/2023	24/03/2023	30/03/2023	04/04/2023	05/04/2023	11/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
B40	17/03/2023	19/03/2023	25/04/2023	21/04/2023	28/04/2023	02/05/2023	04/05/2023	08/05/2023	11/05/2023	12/05/2023	17/05/2023	25/05/2023
B41	17/04/2023	18/04/2023	23/05/2023	17/05/2023	25/05/2023	30/05/2023	01/06/2023	06/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
B42	15/05/2023	16/05/2023	20/06/2023	16/06/2023	22/06/2023	27/06/2023	29/06/2023	04/07/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
B43												
B44	10/07/2023	11/07/2023	14/08/2023	11/08/2023	17/08/2023	22/08/2023	24/08/2023	29/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
B45	07/08/2023	08/08/2023	12/09/2023	08/09/2023	14/09/2023	19/09/2023	21/09/2023	26/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
B46	01/09/2023	02/09/2023	10/10/2023	06/10/2023	12/10/2023	17/10/2023	19/10/2023	24/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
B47	09/10/2023	10/10/2023	14/11/2023	10/11/2023	16/11/2023	21/11/2023	23/11/2023	28/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
B48	20/11/2023	21/11/2023	22/12/2023	21/12/2023	03/01/2024	04/01/2024	05/01/2024	09/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
B49	18/12/2023	19/12/2023	23/01/2024	19/01/2024	25/01/2024	30/01/2024	01/02/2024	06/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
B50	15/01/2024	16/01/2024	20/02/2024	16/02/2024	22/02/2024	27/02/2024	29/02/2024	05/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
B51	19/02/2024	20/02/2024	26/03/2024	22/03/2024	27/03/2024	02/04/2024	04/04/2024	09/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024
B52	25/03/2024	26/03/2024	30/04/2024	26/04/2024	02/05/2024	07/05/2024	08/05/2024	14/05/2024	16/05/2024	17/05/2024	24/05/2024	30/05/2024
B53	22/04/2024	23/04/2024	28/05/2024	24/05/2024	30/05/2024	04/06/2024	06/06/2024	11/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024

	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (^) (**)	CAT Rapporteur(s) Joint) AR (~) (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT List of Outstanding Issues (LoOI) or Opinion	CHMP Opinion (#)
B54	17/05/2024	21/05/2024	25/06/2024	21/06/2024	27/06/2024	02/07/2024	04/07/2024	09/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
B55												
B56	15/07/2024	16/07/2024	20/08/2024	16/08/2024	22/08/2024	27/08/2024	29/08/2024	03/09/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
B57	12/08/2024	13/08/2024	17/09/2024	13/09/2024	19/09/2024	24/09/2024	26/09/2024	01/10/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
B58	09/09/2024	10/09/2024	15/10/2024	11/10/2024	17/10/2024	22/10/2024	24/10/2024	29/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
B59	07/10/2024	08/10/2024	12/11/2024	08/11/2024	14/11/2024	19/11/2024	21/11/2024	26/11/2024	28/11/2024	02/12/2024	06/12/2024	12/12/2024

(\*) 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 if no RMP is submitted (no PRAC involvement).

(\*\*) A Joint assessment report is circulated by the CAT Rapporteur and Co-Rapporteur in case both are involved in the assessment (extension application in support of extension of indication).

(~) Step applicable only if RMP is submitted.

(\*\*\*) Comments from CAT, CHMP and PRAC members are not made available to MAHs.

(#) Step applicable only in case of CAT Opinion (not applicable in case a List of Outstanding Issues is adopted by the CAT).

## Assessment of responses to List of Outstanding Issues (LoOI)

30-day timetable after clock-stop for responses

	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT Opinion	CHMP Opinion
C1	22/01/2020	23/01/2020	06/02/2020	30/01/2020	04/02/2020	06/02/2020	12/02/2020	13/02/2020	17/02/2020	21/02/2020	27/02/2020
C2	19/02/2020	20/02/2020	05/03/2020	27/02/2020	03/03/2020	05/03/2020	11/03/2020	12/03/2020	16/03/2020	20/03/2020	26/03/2020
C3	25/03/2020	26/03/2020	08/04/2020	02/04/2020	07/04/2020	08/04/2020	15/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
C4	20/04/2020	21/04/2020	07/05/2020	30/04/2020	05/05/2020	07/05/2020	13/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
C5	20/05/2020	21/05/2020	04/06/2020	28/05/2020	02/06/2020	04/06/2020	10/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
C6	17/06/2020	18/06/2020	02/07/2020	25/06/2020	30/06/2020	02/07/2020	08/07/2020	09/07/2020	13/07/2020	17/07/2020	23/07/2020
C7											
C8	12/08/2020	13/08/2020	27/08/2020	20/08/2020	25/08/2020	27/08/2020	02/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
C9	09/09/2020	10/09/2020	24/09/2020	17/09/2020	22/09/2020	24/09/2020	30/09/2020	01/10/2020	05/10/2020	09/10/2020	15/10/2020
C10	07/10/2020	08/10/2020	22/10/2020	15/10/2020	20/10/2020	22/10/2020	28/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020
C11	04/11/2020	05/11/2020	19/11/2020	12/11/2020	17/11/2020	19/11/2020	25/11/2020	26/11/2020	30/11/2020	04/12/2020	10/12/2020
C12	23/12/2020	24/12/2020	07/01/2021	04/01/2021	06/01/2021	07/01/2021	13/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
C13	20/01/2021	21/01/2021	04/02/2021	28/01/2021	02/02/2021	04/02/2021	10/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
C14	17/02/2021	18/02/2021	04/03/2021	25/02/2021	02/03/2021	04/03/2021	10/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
C15	17/03/2021	18/03/2021	30/03/2021	25/03/2021	29/03/2021	30/03/2021	07/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
C16	12/04/2021	13/04/2021	29/04/2021	22/04/2021	27/04/2021	29/04/2021	05/05/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
C17	19/05/2021	20/05/2021	03/06/2021	27/05/2021	01/06/2021	03/06/2021	09/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
C18	16/06/2021	17/06/2021	01/07/2021	24/06/2021	29/06/2021	01/07/2021	07/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
C19											
C20	11/08/2021	12/08/2021	26/08/2021	19/08/2021	24/08/2021	26/08/2021	01/09/2021	02/09/2021	06/09/2021	10/09/2021	16/09/2021
C21	08/09/2021	09/09/2021	23/09/2021	16/09/2021	21/09/2021	23/09/2021	29/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
C22	06/10/2021	07/10/2021	21/10/2021	14/10/2021	19/10/2021	21/10/2021	27/10/2021	28/10/2021	29/10/2021	05/11/2021	11/11/2021
C23	10/11/2021	11/11/2021	25/11/2021	18/11/2021	23/11/2021	25/11/2021	01/12/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
C24	22/12/2021	23/12/2021	06/01/2022	03/01/2022	04/01/2022	06/01/2022	12/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022



	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT Opinion	CHMP Opinion
C25	19/01/2022	20/01/2022	03/02/2022	27/01/2022	01/02/2022	03/02/2022	09/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022
C26	16/02/2022	17/02/2022	03/03/2022	24/02/2022	01/03/2022	03/03/2022	09/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
C27	14/03/2022	15/03/2022	31/03/2022	24/03/2022	29/03/2022	31/03/2022	06/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
C28	13/04/2022	14/04/2022	28/04/2022	21/04/2022	26/04/2022	28/04/2022	04/05/2022	05/05/2022	10/05/2022	13/05/2022	19/05/2022
C29	18/05/2022	19/05/2022	02/06/2022	25/05/2022	31/05/2022	02/06/2022	08/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
C30	15/06/2022	16/06/2022	30/06/2022	23/06/2022	28/06/2022	30/06/2022	06/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
C31											
C32	10/08/2022	11/08/2022	25/08/2022	18/08/2022	23/08/2022	25/08/2022	31/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
C33	07/09/2022	08/09/2022	22/09/2022	15/09/2022	20/09/2022	22/09/2022	28/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
C34	05/10/2022	06/10/2022	20/10/2022	13/10/2022	18/10/2022	20/10/2022	26/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
C35	09/11/2022	10/11/2022	24/11/2022	17/11/2022	22/11/2022	24/11/2022	30/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
C36	21/12/2022	22/12/2022	05/01/2023	03/01/2023	04/01/2023	05/01/2023	11/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
C37	18/01/2023	19/01/2023	02/02/2023	26/01/2023	31/01/2023	02/02/2023	08/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
C38	22/02/2023	23/02/2023	09/03/2023	02/03/2023	07/03/2023	09/03/2023	15/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
C39	22/03/2023	23/03/2023	05/04/2023	30/03/2023	04/04/2023	05/04/2023	12/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
C40	17/04/2023	18/04/2023	04/05/2023	26/04/2023	02/05/2023	04/05/2023	10/05/2023	12/05/2023	12/05/2023	17/05/2023	25/05/2023
C41	17/05/2023	18/05/2023	01/06/2023	25/05/2023	30/05/2023	01/06/2023	07/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
C42	14/06/2023	15/06/2023	29/06/2023	22/06/2023	27/06/2023	29/06/2023	05/07/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
C43											
C44	09/08/2023	10/08/2023	24/08/2023	17/08/2023	22/08/2023	24/08/2023	30/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
C45	06/09/2023	07/09/2023	21/09/2023	14/09/2023	19/09/2023	21/09/2023	27/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
C46	29/09/2023	02/10/2023	19/10/2023	12/10/2023	17/10/2023	19/10/2023	25/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
C47	08/11/2023	09/11/2023	23/11/2023	16/11/2023	21/11/2023	23/11/2023	29/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
C48	20/12/2023	21/12/2023	05/01/2024	03/01/2024	04/01/2024	05/01/2024	10/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
C49	17/01/2024	18/01/2024	01/02/2024	25/01/2024	30/01/2024	01/02/2024	07/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
C50	14/02/2024	15/02/2024	29/02/2024	22/02/2024	27/02/2024	29/02/2024	06/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
C51	20/03/2024	21/03/2024	04/04/2024	27/03/2024	02/04/2024	04/04/2024	10/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024

	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Updated PRAC Rapporteur AR (~)	Comments from CAT and CHMP (***)	PRAC outcome (~)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT Opinion	CHMP Opinion
C52	24/04/2024	25/04/2024	08/05/2024	02/05/2024	07/05/2024	08/05/2024	15/05/2024	16/05/2024	21/05/2024	24/05/2024	30/05/2024
C53	22/05/2024	23/05/2024	06/06/2024	30/05/2024	04/06/2024	06/06/2024	12/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
C54	19/06/2024	20/06/2024	04/07/2024	27/06/2024	02/07/2024	04/07/2024	10/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
C55											
C56	14/08/2024	15/08/2024	29/08/2024	22/08/2024	27/08/2024	29/08/2024	04/09/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
C57	11/09/2024	12/09/2024	26/09/2024	19/09/2024	24/09/2024	26/09/2024	02/10/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
C58	09/10/2024	10/10/2024	24/10/2024	17/10/2024	22/10/2024	24/10/2024	30/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
C59	06/11/2024	07/11/2024	21/11/2024	14/11/2024	19/11/2024	21/11/2024	27/11/2024	28/11/2024	02/12/2024	06/12/2024	12/12/2024

(\*) 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.

(\*\*) A Joint assessment report is circulated by the CAT Rapporteur and Co-Rapporteur in case both are involved in the assessment (extension application in support of extension of indication).

(~) Step applicable only if RMP is submitted.

(\*\*\*) Comments from CAT, CHMP and PRAC members are not made available to MAHs.

## Assessment of responses to List of Outstanding Issues (LoOI)

30-day timetable after immediate responses<sup>7</sup>

	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Comments from CAT and CHMP (***)	Updated PRAC Rapporteur AR (~) (^)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT Opinion	CHMP Opinion
D1	30/01/2020	31/01/2020	11/02/2020	11/02/2020	14/02/2020	14/02/2020	17/02/2020	17/02/2020	21/02/2020	27/02/2020
D2	27/02/2020	28/02/2020	10/03/2020	10/03/2020	13/03/2020	13/03/2020	16/03/2020	16/03/2020	20/03/2020	26/03/2020
D3	02/04/2020	03/04/2020	14/04/2020	14/04/2020	17/04/2020	17/04/2020	20/04/2020	20/04/2020	24/04/2020	30/04/2020
D4	28/04/2020	29/04/2020	11/05/2020	11/05/2020	13/05/2020	13/05/2020	15/05/2020	15/05/2020	20/05/2020	28/05/2020
D5	28/05/2020	29/05/2020	09/06/2020	09/06/2020	12/06/2020	12/06/2020	15/06/2020	15/06/2020	19/06/2020	25/06/2020
D6	25/06/2020	26/06/2020	07/07/2020	07/07/2020	10/07/2020	10/07/2020	13/07/2020	13/07/2020	17/07/2020	23/07/2020
D7										
D8	20/08/2020	21/08/2020	01/09/2020	01/09/2020	04/09/2020	04/09/2020	07/09/2020	07/09/2020	11/09/2020	17/09/2020
D9	17/09/2020	18/09/2020	29/09/2020	29/09/2020	02/10/2020	02/10/2020	05/10/2020	05/10/2020	09/10/2020	15/10/2020
D10	15/10/2020	16/10/2020	27/10/2020	27/10/2020	30/10/2020	30/10/2020	03/11/2020	03/11/2020	06/11/2020	12/11/2020
D11	12/11/2020	13/11/2020	24/11/2020	24/11/2020	27/11/2020	27/11/2020	30/11/2020	30/11/2020	04/12/2020	10/12/2020
D12	23/12/2020	01/01/2021	12/01/2021	12/01/2021	15/01/2021	15/01/2021	18/01/2021	18/01/2021	22/01/2021	28/01/2021
D13	28/01/2021	29/01/2021	09/02/2021	09/02/2021	12/02/2021	12/02/2021	15/02/2021	15/02/2021	19/02/2021	25/02/2021
D14	25/02/2021	26/02/2021	09/03/2021	09/03/2021	12/03/2021	12/03/2021	15/03/2021	15/03/2021	19/03/2021	25/03/2021
D15	25/03/2021	26/03/2021	06/04/2021	06/04/2021	09/04/2021	09/04/2021	12/04/2021	12/04/2021	16/04/2021	22/04/2021
D16	20/04/2021	21/04/2021	03/05/2021	03/05/2021	05/05/2021	05/05/2021	07/05/2021	07/05/2021	12/05/2021	20/05/2021
D17	27/05/2021	28/05/2021	08/06/2021	08/06/2021	11/06/2021	11/06/2021	14/06/2021	14/06/2021	18/06/2021	24/06/2021
D18	24/06/2021	25/06/2021	06/07/2021	06/07/2021	09/07/2021	09/07/2021	12/07/2021	12/07/2021	16/07/2021	22/07/2021
D19										
D20	19/08/2021	20/08/2021	31/08/2021	31/08/2021	03/09/2021	03/09/2021	06/09/2021	06/09/2021	10/09/2021	16/09/2021
D21	16/09/2021	17/09/2021	28/09/2021	28/09/2021	01/10/2021	01/10/2021	04/10/2021	04/10/2021	08/10/2021	14/10/2021
D22	14/10/2021	15/10/2021	26/10/2021	26/10/2021	29/10/2021	29/10/2021	29/10/2021	29/10/2021	05/11/2021	11/11/2021
D23	18/11/2021	19/11/2021	30/11/2021	30/11/2021	03/12/2021	03/12/2021	06/12/2021	06/12/2021	10/12/2021	16/12/2021
D24	22/12/2021	23/12/2021	11/01/2022	11/01/2022	14/01/2022	14/01/2022	17/01/2022	17/01/2022	21/01/2022	27/01/2022

	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Comments from CAT and CHMP (***)	Updated PRAC Rapporteur AR (~) (^)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT Opinion	CHMP Opinion
D25	27/01/2022	28/01/2022	08/02/2022	08/02/2022	11/02/2022	11/02/2022	14/02/2022	14/02/2022	18/02/2022	24/02/2022
D26	24/02/2022	25/02/2022	08/03/2022	08/03/2022	11/03/2022	11/03/2022	14/03/2022	14/03/2022	18/03/2022	24/03/2022
D27	22/03/2022	23/03/2022	04/04/2022	04/04/2022	06/04/2022	06/04/2022	08/04/2022	08/04/2022	13/04/2022	22/04/2022
D28	21/04/2022	22/04/2022	03/05/2022	03/05/2022	06/05/2022	06/05/2022	10/05/2022	10/05/2022	13/05/2022	19/05/2022
D29	20/05/2022	23/05/2022	07/06/2022	07/06/2022	10/06/2022	10/06/2022	13/06/2022	13/06/2022	17/06/2022	23/06/2022
D30	23/06/2022	24/06/2022	05/07/2022	05/07/2022	08/07/2022	08/07/2022	11/07/2022	11/07/2022	15/07/2022	21/07/2022
D31										
D32	10/08/2022	11/08/2022	30/08/2022	30/08/2022	02/09/2022	02/09/2022	05/09/2022	05/09/2022	09/09/2022	15/09/2022
D33	15/09/2022	16/09/2022	27/09/2022	27/09/2022	30/09/2022	30/09/2022	03/10/2022	03/10/2022	07/10/2022	13/10/2022
D34	13/10/2022	14/10/2022	25/10/2022	25/10/2022	27/10/2022	27/10/2022	28/10/2022	28/10/2022	04/11/2022	10/11/2022
D35	11/11/2022	14/11/2022	29/11/2022	29/11/2022	02/12/2022	02/12/2022	05/12/2022	05/12/2022	09/12/2022	15/12/2022
D36	21/12/2022	22/12/2022	10/01/2023	10/01/2023	13/01/2023	13/01/2023	16/01/2023	16/01/2023	20/01/2023	26/01/2023
D37	26/01/2023	27/01/2023	07/02/2023	07/02/2023	10/02/2023	10/02/2023	13/02/2023	13/02/2023	17/02/2023	23/02/2023
D38	24/02/2023	27/02/2023	14/03/2023	14/03/2023	17/03/2023	17/03/2023	20/03/2023	20/03/2023	24/03/2023	30/03/2023
D39	30/03/2023	31/03/2023	11/04/2023	11/04/2023	14/04/2023	14/04/2023	17/04/2023	17/04/2023	21/04/2023	26/04/2023
D40	25/04/2023	26/04/2023	08/05/2023	08/05/2023	10/05/2023	10/05/2023	12/05/2023	12/05/2023	17/05/2023	25/05/2023
D41	25/05/2023	26/05/2023	06/06/2023	06/06/2023	09/06/2023	09/06/2023	12/06/2023	12/06/2023	16/06/2023	22/06/2023
D42	22/06/2023	23/06/2023	04/07/2023	04/07/2023	07/07/2023	07/07/2023	10/07/2023	10/07/2023	14/07/2023	20/07/2023
D43										
D44	09/08/2023	10/08/2023	29/08/2023	29/08/2023	01/09/2023	01/09/2023	04/09/2023	04/09/2023	08/09/2023	14/09/2023
D45	14/09/2023	15/09/2023	26/09/2023	26/09/2023	29/09/2023	29/09/2023	02/10/2023	02/10/2023	06/10/2023	12/10/2023
D46	09/10/2023	10/10/2023	20/10/2023	20/10/2023	24/10/2023	24/10/2023	27/10/2023	27/10/2023	31/10/2023	09/11/2023
D47	08/11/2023	09/11/2023	28/11/2023	28/11/2023	01/12/2023	01/12/2023	04/12/2023	04/12/2023	08/12/2023	14/12/2023
D48	20/12/2023	21/12/2023	09/01/2024	09/01/2024	12/01/2024	12/01/2024	15/01/2024	15/01/2024	19/01/2024	25/01/2024
D49	25/01/2024	26/01/2024	06/02/2024	06/02/2024	09/02/2024	09/02/2024	12/02/2024	12/02/2024	16/02/2024	22/02/2024
D50	22/02/2024	23/02/2024	05/03/2024	05/03/2024	08/03/2024	08/03/2024	11/03/2024	11/03/2024	15/03/2024	21/03/2024
D51	22/03/2024	25/03/2024	09/04/2024	09/04/2024	12/04/2024	12/04/2024	15/04/2024	15/04/2024	19/04/2024	25/04/2024

	Deadline for Submission (*)	Restart	CAT Rapporteur(s) Joint) AR (**)	PRAC Rapporteur AR (~)	Comments from PRAC (***) (~)	Comments from CAT and CHMP (***)	Updated PRAC Rapporteur AR (~) (^)	Updated CAT Rapporteur(s) Joint) AR (**)	CAT Opinion	CHMP Opinion
D52	26/04/2024	29/04/2024	14/05/2024	14/05/2024	17/05/2024	17/05/2024	21/05/2024	21/05/2024	24/05/2024	30/05/2024
D53	30/05/2024	31/05/2024	11/06/2024	11/06/2024	14/06/2024	14/06/2024	17/06/2024	17/06/2024	21/06/2024	27/06/2024
D54	27/06/2024	28/06/2024	09/07/2024	09/07/2024	12/07/2024	12/07/2024	15/07/2024	15/07/2024	19/07/2024	25/07/2024
D55										
D56	14/08/2024	15/08/2024	03/09/2024	03/09/2024	06/09/2024	06/09/2024	09/09/2024	09/09/2024	13/09/2024	19/09/2024
D57	19/09/2024	20/09/2024	01/10/2024	01/10/2024	04/10/2024	04/10/2024	07/10/2024	07/10/2024	11/10/2024	17/10/2024
D58	17/10/2024	18/10/2024	29/10/2024	29/10/2024	31/10/2024	31/10/2024	04/11/2024	04/11/2024	08/11/2024	14/11/2024
D59	14/11/2024	15/11/2024	26/11/2024	26/11/2024	29/11/2024	29/11/2024	02/12/2024	02/12/2024	06/12/2024	12/12/2024

(-) This timetable is only used exceptionally and after agreement with the Rapporteurs when minor issues remain which allow the applicant to respond shortly after the CAT list of questions and the Rapporteurs to assess the responses within a shortened assessment time.

(\*) 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 RMP is submitted.

(^) A PRAC discussion is not foreseen in this timetable; PRAC member comments are reflected in the updated PRAC Rapporteur assessment report.

(\*\*) A Joint assessment report is circulated by the CAT Rapporteur and Co-Rapporteur in case both are involved in the assessment (extension application in support of extension of indication).

(\*\*\*) Comments from CAT, CHMP and PRAC members are not made available to Applicants.