

31 October 2017  
EMA/824995/2015 Rev. 1  
Human Medicines Evaluation

[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	02/01/2017	19/01/2017	08/04/2017	18/04/2017	24/04/2017	27/04/2017	28/04/2017	05/05/2017	08/05/2017	12/05/2017	18/05/2017
A2	06/02/2017	23/02/2017	13/05/2017	23/05/2017	29/05/2017	01/06/2017	02/06/2017	09/06/2017	12/06/2017	16/06/2017	22/06/2017
A3	06/03/2017	23/03/2017	10/06/2017	20/06/2017	26/06/2017	29/06/2017	30/06/2017	06/07/2017	10/07/2017	14/07/2017	20/07/2017
A4											
A5	27/04/2017	18/05/2017	05/08/2017	15/08/2017	21/08/2017	24/08/2017	25/08/2017	01/09/2017	04/09/2017	08/09/2017	14/09/2017
A6	24/05/2017	15/06/2017	02/09/2017	12/09/2017	18/09/2017	21/09/2017	22/09/2017	28/09/2017	02/10/2017	06/10/2017	12/10/2017
A7	26/06/2017	13/07/2017	30/09/2017	10/10/2017	16/10/2017	19/10/2017	20/10/2017	26/10/2017	27/10/2017	31/10/2017	09/11/2017
A8	31/07/2017	17/08/2017	04/11/2017	14/11/2017	20/11/2017	23/11/2017	24/11/2017	30/11/2017	04/12/2017	08/12/2017	14/12/2017
A9	11/09/2017	28/09/2017	16/12/2017	03/01/2018	04/01/2018	05/01/2018	05/01/2018	11/01/2018	15/01/2018	19/01/2018	25/01/2018
A10	09/10/2017	26/10/2017	15/01/2018	23/01/2018	29/01/2018	01/02/2018	02/02/2018	08/02/2018	12/02/2018	16/02/2018	22/02/2018
A11	06/11/2017	23/11/2017	12/02/2018	20/02/2018	26/02/2018	01/03/2018	02/03/2018	08/03/2018	12/03/2018	16/03/2018	22/03/2018
A12	27/11/2017	28/12/2017	19/03/2018	27/03/2018	03/04/2018	05/04/2018	06/04/2018	12/04/2018	16/04/2018	20/04/2018	26/04/2018
A13	15/01/2018	01/02/2018	23/04/2018	02/05/2018	07/05/2018	10/05/2018	11/05/2018	17/05/2018	21/05/2018	25/05/2018	31/05/2018
A14	12/02/2018	01/03/2018	22/05/2018	29/05/2018	04/06/2018	07/06/2018	08/06/2018	14/06/2018	18/06/2018	22/06/2018	28/06/2018
A15	08/03/2018	29/03/2018	18/06/2018	26/06/2018	02/07/2018	05/07/2018	06/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
A16											
A17	30/04/2018	24/05/2018	13/08/2018	21/08/2018	27/08/2018	30/08/2018	31/08/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
A18	04/06/2018	21/06/2018	10/09/2018	18/09/2018	24/09/2018	27/09/2018	28/09/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
A19	02/07/2018	19/07/2018	08/10/2018	16/10/2018	22/10/2018	25/10/2018	26/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
A20	30/07/2018	16/08/2018	05/11/2018	13/11/2018	19/11/2018	22/11/2018	23/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018
A21	17/09/2018	04/10/2018	20/12/2018	03/01/2019	08/01/2019	10/01/2019	11/01/2019	17/01/2019	21/01/2019	25/01/2019	31/01/2019
A22	15/10/2018	01/11/2018	21/01/2019	29/01/2019	04/02/2019	07/02/2019	08/02/2019	14/02/2019	18/02/2019	22/02/2019	28/02/2019
A23	12/11/2018	29/11/2018	18/02/2019	26/02/2019	04/03/2019	07/03/2019	08/03/2019	14/03/2019	18/03/2019	22/03/2019	28/03/2019
A24	26/11/2018	25/12/2018	18/03/2019	26/03/2019	01/04/2019	04/04/2019	05/04/2019	11/04/2019	12/04/2019	17/04/2019	26/04/2019

	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 (#)
A25	14/01/2019	31/01/2019	23/04/2019	29/04/2019	06/05/2019	08/05/2019	10/05/2019	16/05/2019	20/05/2019	24/05/2019	29/05/2019
A26	11/02/2019	28/02/2019	20/05/2019	28/05/2019	03/06/2019	06/06/2019	07/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
A27	11/03/2019	28/03/2019	17/06/2019	25/06/2019	01/07/2019	04/07/2019	05/07/2019	11/07/2019	15/07/2019	19/07/2019	25/07/2019
A28											
A29	06/05/2019	23/05/2019	12/08/2019	20/08/2019	27/08/2019	29/08/2019	30/08/2019	05/09/2019	09/09/2019	13/09/2019	19/09/2019
A30	03/06/2019	20/06/2019	09/09/2019	17/09/2019	23/09/2019	26/09/2019	27/09/2019	03/10/2019	07/10/2019	11/10/2019	17/10/2019
A31	01/07/2019	18/07/2019	07/10/2019	15/10/2019	21/10/2019	24/10/2019	25/10/2019	31/10/2019	04/11/2019	08/11/2019	14/11/2019
A33	29/07/2019	15/08/2019	04/11/2019	12/11/2019	18/11/2019	21/11/2019	22/11/2019	28/11/2019	02/12/2019	06/12/2019	12/12/2019
A34	16/09/2019	03/10/2019	19/12/2019	03/01/2020	07/01/2020	09/01/2020	10/01/2020	16/01/2020	20/01/2020	24/01/2020	30/01/2020
A35	14/10/2019	31/10/2019	20/01/2020	28/01/2020	03/02/2020	06/02/2020	07/02/2020	13/02/2020	17/02/2020	21/02/2020	27/02/2020
A36	11/11/2019	28/11/2019	17/02/2020	25/02/2020	02/03/2020	05/03/2020	06/03/2020	12/03/2020	16/03/2020	20/03/2020	26/03/2020
A37	25/11/2019	02/01/2020	23/03/2020	31/03/2020	06/04/2020	07/04/2020	08/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
A38	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
A39	10/02/2020	27/02/2020	18/05/2020	26/05/2020	01/06/2020	04/06/2020	05/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
A40	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
A41											
A42	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
A43	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
A45	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
A46	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
A47	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
A48	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
A49	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
A50	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
A51	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
A52	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

	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	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
A54											
A55	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
A56	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
A57	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
A58	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

(\*) 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	16/01/2017	17/01/2017	21/02/2017	17/02/2017	23/02/2017	28/02/2017	02/03/2017	07/03/2017	09/03/2017	13/03/2017	17/03/2017	23/03/2017
B2	10/02/2017	12/02/2017	20/03/2017	15/03/2017	21/03/2017	28/03/2017	30/03/2017	03/04/2017	06/04/2017	07/04/2017	12/04/2017	21/04/2017
B3	13/03/2017	14/03/2017	18/04/2017	12/04/2017	20/04/2017	25/04/2017	27/04/2017	02/05/2017	05/05/2017	08/05/2017	12/05/2017	18/05/2017
B4	17/04/2017	18/04/2017	23/05/2017	19/05/2017	24/05/2017	30/05/2017	01/06/2017	06/06/2017	09/06/2017	12/06/2017	16/06/2017	22/06/2017
B5	15/05/2017	16/05/2017	20/06/2017	16/06/2017	22/06/2017	27/06/2017	29/06/2017	04/07/2017	06/07/2017	10/07/2017	14/07/2017	20/07/2017
B6												
B7	10/07/2017	11/07/2017	15/08/2017	11/08/2017	17/08/2017	22/08/2017	24/08/2017	29/08/2017	01/09/2017	04/09/2017	08/09/2017	14/09/2017
B8	07/08/2017	08/08/2017	12/09/2017	08/09/2017	14/09/2017	19/09/2017	21/09/2017	26/09/2017	28/09/2017	02/10/2017	06/10/2017	12/10/2017
B9	01/09/2017	02/09/2017	06/10/2017	03/10/2017	09/10/2017	17/10/2017	19/10/2017	23/10/2017	26/10/2017	27/10/2017	31/10/2017	09/11/2017
B10	09/10/2017	10/10/2017	14/11/2017	10/11/2017	16/11/2017	21/11/2017	23/11/2017	28/11/2017	30/11/2017	04/12/2017	08/12/2017	14/12/2017
B11	20/11/2017	21/11/2017	21/12/2017	21/12/2017	03/01/2018	04/01/2018	05/01/2018	09/01/2018	11/01/2018	15/01/2018	19/01/2018	25/01/2018
B12	18/12/2017	19/12/2017	23/01/2018	19/01/2018	25/01/2018	30/01/2018	01/02/2018	06/02/2018	08/02/2018	12/02/2018	16/02/2018	22/02/2018
B13	15/01/2018	16/01/2018	20/02/2018	16/02/2018	22/02/2018	27/02/2018	01/03/2018	06/03/2018	08/03/2018	12/03/2018	16/03/2018	22/03/2018
B14	19/02/2018	20/02/2018	27/03/2018	23/03/2018	28/03/2018	04/04/2018	05/04/2018	10/04/2018	12/04/2018	16/04/2018	20/04/2018	26/04/2018
B15	26/03/2018	27/03/2018	02/05/2018	27/04/2018	03/05/2018	07/05/2018	08/05/2018	15/05/2018	17/05/2018	22/05/2018	25/05/2018	31/05/2018
B16	23/04/2018	24/04/2018	29/05/2018	25/05/2018	31/05/2018	05/06/2018	07/06/2018	12/06/2018	14/06/2018	18/06/2018	22/06/2018	28/06/2018
B17	18/05/2018	22/05/2018	26/06/2018	22/06/2018	28/06/2018	03/07/2018	05/07/2018	10/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
B18												
B19	16/07/2018	17/07/2018	21/08/2018	17/08/2018	23/08/2018	28/08/2018	30/08/2018	04/09/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
B20	13/08/2018	14/08/2018	18/09/2018	14/09/2018	20/09/2018	25/09/2018	27/09/2018	02/10/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
B21	10/09/2018	11/09/2018	16/10/2018	12/10/2018	18/10/2018	23/10/2018	25/10/2018	30/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
B22	08/10/2018	09/10/2018	13/11/2018	09/11/2018	15/11/2018	20/11/2018	22/11/2018	27/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018
B23	26/11/2018	27/11/2018	03/01/2019	20/12/2018	03/01/2019	08/01/2019	10/01/2019	15/01/2019	17/01/2019	21/01/2019	25/01/2019	31/01/2019
B24	21/12/2018	25/12/2018	29/01/2019	25/01/2019	31/01/2019	05/02/2019	07/02/2019	12/02/2019	14/02/2019	18/02/2019	22/02/2019	28/02/2019
B25	21/01/2019	22/01/2019	26/02/2019	22/02/2019	28/02/2019	05/03/2019	07/03/2019	12/03/2019	14/03/2019	18/03/2019	22/03/2019	28/03/2019
B26	15/02/2019	17/02/2019	26/03/2019	22/03/2019	28/03/2019	02/04/2019	04/04/2019	09/04/2019	11/04/2019	12/04/2019	17/04/2019	26/04/2019
B27	25/03/2019	26/03/2019	30/04/2019	26/04/2019	02/05/2019	07/05/2019	08/05/2019	14/05/2019	16/05/2019	20/05/2019	24/05/2019	29/05/2019

	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 (#)
B28	18/04/2019	23/04/2019	28/05/2019	24/05/2019	29/05/2019	04/06/2019	06/06/2019	11/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
B29	20/05/2019	21/05/2019	25/06/2019	21/06/2019	27/06/2019	02/07/2019	04/07/2019	09/07/2019	11/07/2019	15/07/2019	19/07/2019	25/07/2019
B30												
B31	15/07/2019	16/07/2019	20/08/2019	16/08/2019	22/08/2019	27/08/2019	29/08/2019	03/09/2019	05/09/2019	09/09/2019	13/09/2019	19/09/2019
B32	12/08/2019	13/08/2019	17/09/2019	13/09/2019	19/09/2019	24/09/2019	26/09/2019	01/10/2019	03/10/2019	07/10/2019	11/10/2019	17/10/2019
B33	09/09/2019	10/09/2019	15/10/2019	11/10/2019	17/10/2019	22/10/2019	24/10/2019	29/10/2019	31/10/2019	04/11/2019	08/11/2019	14/11/2019
B34	07/10/2019	08/10/2019	12/11/2019	08/11/2019	14/11/2019	19/11/2019	21/11/2019	26/11/2019	28/11/2019	02/12/2019	06/12/2019	12/12/2019
B35	25/11/2019	26/11/2019	03/01/2020	20/12/2019	03/01/2020	07/01/2020	09/01/2020	14/01/2020	16/01/2020	20/01/2020	24/01/2020	30/01/2020
B36	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
B37	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
B38	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
B39	20/03/2020	22/03/2020	28/04/2020	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
B40	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
B41	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
B42												
B43	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
B44	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
B45	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
B46	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
B47	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
B48	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
B49	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
B50	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
B51	12/03/2021	14/03/2021	20/04/2021	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
B52	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
B53	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
B54												
B55	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
B56	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
B57	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

	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 (#)
B58	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

(\*) 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	18/01/2017	19/01/2017	02/02/2017	26/01/2017	31/01/2017	02/02/2017	08/02/2017	09/02/2017	13/02/2017	17/02/2017	23/02/2017
C2	15/02/2017	16/02/2017	02/03/2017	23/02/2017	28/02/2017	02/03/2017	08/03/2017	09/03/2017	13/03/2017	17/03/2017	23/03/2017
C3	13/03/2017	14/03/2017	28/03/2017	21/03/2017	27/03/2017	28/03/2017	03/04/2017	06/04/2017	07/04/2017	12/04/2017	21/04/2017
C4	12/04/2017	13/04/2017	27/04/2017	20/04/2017	25/04/2017	27/04/2017	03/05/2017	05/05/2017	08/05/2017	12/05/2017	18/05/2017
C5	17/05/2017	18/05/2017	01/06/2017	24/05/2017	30/05/2017	01/06/2017	07/06/2017	09/06/2017	12/06/2017	16/06/2017	22/06/2017
C6	14/06/2017	15/06/2017	29/06/2017	22/06/2017	27/06/2017	29/06/2017	05/07/2017	06/07/2017	10/07/2017	14/07/2017	20/07/2017
C7											
C8	09/08/2017	10/08/2017	24/08/2017	17/08/2017	22/08/2017	24/08/2017	30/08/2017	01/09/2017	04/09/2017	08/09/2017	14/09/2017
C9	06/09/2017	07/09/2017	21/09/2017	14/09/2017	19/09/2017	21/09/2017	27/09/2017	28/09/2017	02/10/2017	06/10/2017	12/10/2017
C10	29/09/2017	02/10/2017	16/10/2017	09/10/2017	13/10/2017	16/10/2017	22/10/2017	26/10/2017	27/10/2017	31/10/2017	09/11/2017
C11	08/11/2017	09/11/2017	23/11/2017	16/11/2017	21/11/2017	23/11/2017	29/11/2017	30/11/2017	04/12/2017	08/12/2017	14/12/2017
C12	20/12/2017	21/12/2017	05/01/2018	03/01/2018	04/01/2018	05/01/2018	10/01/2018	11/01/2018	15/01/2018	19/01/2018	25/01/2018
C13	17/01/2018	18/01/2018	01/02/2018	25/01/2018	30/01/2018	01/02/2018	07/02/2018	08/02/2018	12/02/2018	16/02/2018	22/02/2018
C14	14/02/2018	15/02/2018	01/03/2018	22/02/2018	27/02/2018	01/03/2018	07/03/2018	08/03/2018	12/03/2018	16/03/2018	22/03/2018
C15	21/03/2018	22/03/2018	05/04/2018	28/03/2018	03/04/2018	05/04/2018	11/04/2018	12/04/2018	16/04/2018	20/04/2018	26/04/2018
C16	25/04/2018	26/04/2018	08/05/2018	03/05/2018	07/05/2018	08/05/2018	16/05/2018	17/05/2018	22/05/2018	25/05/2018	31/05/2018
C17	23/05/2018	24/05/2018	07/06/2018	31/05/2018	05/06/2018	07/06/2018	13/06/2018	14/06/2018	18/06/2018	22/06/2018	28/06/2018
C18	20/06/2018	21/06/2018	05/07/2018	28/06/2018	03/07/2018	05/07/2018	11/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
C19											
C20	15/08/2018	16/08/2018	30/08/2018	23/08/2018	28/08/2018	30/08/2018	05/09/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
C21	12/09/2018	13/09/2018	27/09/2018	20/09/2018	25/09/2018	27/09/2018	03/10/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
C22	10/10/2018	11/10/2018	25/10/2018	18/10/2018	23/10/2018	25/10/2018	31/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
C23	07/11/2018	08/11/2018	22/11/2018	15/11/2018	20/11/2018	22/11/2018	28/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018



	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
C24	21/12/2018	27/12/2018	10/01/2019	03/01/2019	08/01/2019	10/01/2019	16/01/2019	17/01/2019	21/01/2019	25/01/2019	31/01/2019
C25	23/01/2019	24/01/2019	07/02/2019	31/01/2019	05/02/2019	07/02/2019	13/02/2019	14/02/2019	18/02/2019	22/02/2019	28/02/2019
C26	20/02/2019	21/02/2019	07/03/2019	28/02/2019	05/03/2019	07/03/2019	13/03/2019	14/03/2019	18/03/2019	22/03/2019	28/03/2019
C27	18/03/2019	19/03/2019	04/04/2019	28/03/2019	02/04/2019	04/04/2019	10/04/2019	11/04/2019	12/04/2019	17/04/2019	26/04/2019
C28	24/04/2019	25/04/2019	08/05/2019	02/05/2019	07/05/2019	08/05/2019	15/05/2019	16/05/2019	20/05/2019	24/05/2019	29/05/2019
C29	22/05/2019	23/05/2019	06/06/2019	29/05/2019	04/06/2019	06/06/2019	12/06/2019	14/06/2019	17/06/2019	21/06/2019	27/06/2019
C30	19/06/2019	20/06/2019	04/07/2019	27/06/2019	02/07/2019	04/07/2019	10/07/2019	11/07/2019	15/07/2019	19/07/2019	25/07/2019
C31											
C32	14/08/2019	15/08/2019	29/08/2019	22/08/2019	27/08/2019	29/08/2019	04/09/2019	05/09/2019	09/09/2019	13/09/2019	19/09/2019
C33	11/09/2019	12/09/2019	26/09/2019	19/09/2019	24/09/2019	26/09/2019	02/10/2019	03/10/2019	07/10/2019	11/10/2019	17/10/2019
C34	09/10/2019	10/10/2019	24/10/2019	17/10/2019	22/10/2019	24/10/2019	30/10/2019	31/10/2019	04/11/2019	08/11/2019	14/11/2019
C35	06/11/2019	07/11/2019	21/11/2019	14/11/2019	19/11/2019	21/11/2019	27/11/2019	28/11/2019	02/12/2019	06/12/2019	12/12/2019
C36	23/12/2019	26/12/2019	09/01/2020	03/01/2020	07/01/2020	09/01/2020	15/01/2020	16/01/2020	20/01/2020	24/01/2020	30/01/2020
C37	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
C38	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
C39	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
C40	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
C41	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
C42	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
C43											
C44	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
C45	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
C46	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
C47	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
C48	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
C49	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

	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
C50	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
C51	17/03/2021	18/03/2021	01/04/2021	25/03/2021	30/03/2021	01/04/2021	07/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
C52	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
C53	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
C54	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
C55											
C56	11/08/2021	12/08/2021	26/08/2021	19/08/2021	24/08/2021	26/08/2021	01/09/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
C57	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
C58	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
C59	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

(\*) 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	26/01/2017	27/01/2017	07/02/2017	07/02/2017	10/02/2017	10/02/2017	13/02/2017	13/02/2017	17/02/2017	23/02/2017
D2	23/02/2017	24/02/2017	07/03/2017	07/03/2017	10/03/2017	10/03/2017	13/03/2017	13/03/2017	17/03/2017	23/03/2017
D3	21/03/2017	22/03/2017	03/04/2017	03/04/2017	05/04/2017	05/04/2017	07/04/2017	07/04/2017	12/04/2017	21/04/2017
D4	20/04/2017	21/04/2017	02/05/2017	02/05/2017	05/05/2017	05/05/2017	08/05/2017	08/05/2017	12/05/2017	18/05/2017
D5	24/05/2017	26/05/2017	06/06/2017	06/06/2017	09/06/2017	09/06/2017	12/06/2017	12/06/2017	16/06/2017	22/06/2017
D6	22/06/2017	23/06/2017	04/07/2017	04/07/2017	07/07/2017	07/07/2017	10/07/2017	10/07/2017	14/07/2017	20/07/2017
D7										
D8										
D9	14/09/2017	15/09/2017	26/09/2017	26/09/2017	29/09/2017	29/09/2017	02/10/2017	02/10/2017	06/10/2017	12/10/2017
D10	09/10/2017	10/10/2017	20/10/2017	20/10/2017	24/10/2017	24/10/2017	27/10/2017	27/10/2017	31/10/2017	09/11/2017
D11	16/11/2017	17/11/2017	28/11/2017	28/11/2017	01/12/2017	01/12/2017	04/12/2017	04/12/2017	08/12/2017	14/12/2017
D12	22/12/2017	29/12/2017	09/01/2018	09/01/2018	12/01/2018	12/01/2018	15/01/2018	15/01/2018	19/01/2018	25/01/2018
D13	25/01/2018	26/01/2018	06/02/2018	06/02/2018	09/02/2018	09/02/2018	12/02/2018	12/02/2018	16/02/2018	22/02/2018
D14	22/02/2017	23/02/2018	06/03/2018	06/03/2018	09/03/2018	09/03/2018	12/03/2018	12/03/2018	16/03/2018	22/03/2018
D15	28/03/2018	30/03/2018	10/04/2018	10/04/2018	13/04/2018	13/04/2018	16/04/2018	16/04/2018	20/04/2018	26/04/2018
D16	03/05/2018	04/05/2018	15/05/2018	15/05/2018	18/05/2018	18/05/2018	22/05/2018	22/05/2018	25/05/2018	31/05/2018
D17	31/05/2018	01/06/2018	12/06/2018	12/06/2018	15/06/2018	15/06/2018	18/06/2018	18/06/2018	22/06/2018	28/06/2018
D18	28/06/2018	29/06/2018	10/07/2018	10/07/2018	13/07/2018	13/07/2018	16/07/2018	16/07/2018	20/07/2018	26/07/2018
D19										
D20										
D21	20/09/2018	21/09/2018	02/10/2018	02/10/2018	05/10/2018	05/10/2018	08/10/2018	08/10/2018	12/10/2018	18/10/2018
D22	18/10/2018	19/10/2018	30/10/2018	30/10/2018	31/10/2018	31/10/2018	05/11/2018	05/11/2018	09/11/2018	15/11/2018
D23	15/11/2018	16/11/2018	27/11/2018	27/11/2018	30/11/2018	30/11/2018	03/12/2018	03/12/2018	07/12/2018	13/12/2018

	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
D24	03/01/2019	04/01/2019	15/01/2019	15/01/2019	18/01/2019	18/01/2019	21/01/2019	21/01/2019	25/01/2019	31/01/2019
D25	31/01/2019	01/02/2019	12/02/2019	12/02/2019	15/02/2019	15/02/2019	18/02/2019	18/02/2019	22/02/2019	28/02/2019
D26	28/02/2019	01/03/2019	12/03/2019	12/03/2019	15/03/2019	15/03/2019	18/03/2019	18/03/2019	22/03/2019	28/03/2019
D27	26/03/2019	27/03/2019	08/04/2019	08/04/2019	10/04/2019	10/04/2019	12/04/2019	12/04/2019	17/04/2019	26/04/2019
D28	02/05/2019	03/05/2019	14/05/2019	14/05/2019	17/05/2019	17/05/2019	20/05/2019	20/05/2019	24/05/2019	29/05/2019
D29	29/05/2019	31/05/2019	11/06/2019	11/06/2019	14/06/2019	14/06/2019	17/06/2019	17/06/2019	21/06/2019	27/06/2019
D30	27/06/2019	28/06/2019	09/07/2019	09/07/2019	12/07/2019	12/07/2019	15/07/2019	15/07/2019	19/07/2019	25/07/2019
D31										
D32										
D33	19/09/2019	20/09/2019	01/10/2019	01/10/2019	04/10/2019	04/10/2019	07/10/2019	07/10/2019	11/10/2019	17/10/2019
D34	17/10/2019	18/10/2019	29/10/2019	29/10/2019	30/10/2019	30/10/2019	04/11/2019	04/11/2019	08/11/2019	14/11/2019
D35	14/11/2019	15/11/2019	26/11/2019	26/11/2019	29/11/2019	29/11/2019	02/12/2019	02/12/2019	06/12/2019	12/12/2019
D36	23/12/2020	03/01/2020	14/01/2020	14/01/2020	17/01/2020	17/01/2020	20/01/2020	20/01/2020	24/01/2020	30/01/2020
D37	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
D38	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
D39	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
D40	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
D41	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
D42	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
D43										
D44										
D45	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
D46	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
D47	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
D48	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
D49	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

	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
D50	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
D51	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
D52	20/04/2021	21/04/2021	02/05/2021	02/05/2021	05/05/2021	05/05/2021	07/05/2021	07/05/2021	12/05/2021	20/05/2021
D53	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
D54	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
D55										
D56										
D57	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
D58	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
D59	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

(~) 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.