



01 February 2021
EMA/51610/2021
Human Medicines Division

The timetables in this document may be subject to revision

Initial (Full) Marketing Authorisation application accelerated assessment timetables Advanced therapy medicinal product (ATMP)

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

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

Assessment of initial submission (120-day timetable)

	Deadline for Submission (*)	Start date (^)	CAT (Co) Rapporteur ARs	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CAT and CHMP (**)	Early draft LOQ (for Peer review tele-conference) (#)	PRAC outcome	Updated PRAC Rapporteur AR	Peer review telecon-ference (TC)	Draft LoQ	CAT List of Questions (LoQ) or draft Opinion	CHMP Opinion (~)
A1	13/01/2020	28/01/2020	20/04/2020	04/05/2020	08/05/2020	08/05/2020	13/05/2020	14/05/2020	14/05/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
A2	10/02/2020	27/02/2020	18/05/2020	01/06/2020	05/06/2020	05/06/2020	10/06/2020	11/06/2020	11/06/2020	11/06/2020	15/06/2020	19/06/2020	25/06/2020
A3	09/03/2020	26/03/2020	15/06/2020	29/06/2020	03/07/2020	03/07/2020	08/07/2020	09/07/2020	09/07/2020	09/07/2020	13/07/2020	17/07/2020	23/07/2020
A4													
A5	04/05/2020	21/05/2020	10/08/2020	24/08/2020	28/08/2020	28/08/2020	02/09/2020	04/09/2020	04/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
A6	01/06/2020	18/06/2020	07/09/2020	21/09/2020	25/09/2020	25/09/2020	30/09/2020	01/10/2020	01/10/2020	01/10/2020	05/10/2020	09/10/2020	15/10/2020
A7	29/06/2020	16/07/2020	05/10/2020	19/10/2020	23/10/2020	23/10/2020	28/10/2020	29/10/2020	29/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020
A8	27/07/2020	13/08/2020	03/11/2020	16/11/2020	20/11/2020	20/11/2020	25/11/2020	26/11/2020	26/11/2020	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	08/01/2021	08/01/2021	13/01/2021	14/01/2021	14/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
A10	12/10/2020	29/10/2020	18/01/2021	01/02/2021	05/02/2021	05/02/2021	10/02/2021	11/02/2021	11/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
A11	09/11/2020	26/11/2020	15/02/2021	01/03/2021	05/03/2021	05/03/2021	10/03/2021	11/03/2021	11/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
A12	23/11/2020	24/12/2020	15/03/2021	29/03/2021	31/03/2021	31/03/2021	07/04/2021	09/04/2021	09/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
A13	04/01/2021	19/01/2021	12/04/2021	26/04/2021	30/04/2021	30/04/2021	05/05/2021	06/05/2021	06/05/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
A14	08/02/2021	25/02/2021	17/05/2021	31/05/2021	04/06/2021	04/06/2021	09/06/2021	10/06/2021	10/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
A15	08/03/2021	25/03/2021	14/06/2021	28/06/2021	02/07/2021	02/07/2021	07/07/2021	08/07/2021	08/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
A16													
A17	30/04/2021	20/05/2021	09/08/2021	23/08/2021	27/08/2021	27/08/2021	01/09/2021	03/09/2021	03/09/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
A18	31/05/2021	17/06/2021	06/09/2021	20/09/2021	24/09/2021	24/09/2021	29/09/2021	30/09/2021	30/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
A19	28/06/2021	15/07/2021	04/10/2021	18/10/2021	22/10/2021	22/10/2021	27/10/2021	28/10/2021	28/10/2021	28/10/2021	29/10/2021	05/11/2021	11/11/2021
A20	02/08/2021	19/08/2021	08/11/2021	22/11/2021	26/11/2021	26/11/2021	01/12/2021	02/12/2021	02/12/2021	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	07/01/2022	07/01/2022	12/01/2022	13/01/2022	13/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
A22	11/10/2021	28/10/2021	17/01/2022	31/01/2022	04/02/2022	04/02/2022	09/02/2022	10/02/2022	10/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022
A23	08/11/2021	25/11/2021	14/02/2022	28/02/2022	04/03/2022	04/03/2022	09/03/2022	10/03/2022	10/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
A24	29/11/2021	21/12/2021	14/03/2022	28/03/2022	01/04/2022	01/04/2022	06/04/2022	07/04/2022	07/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
A25	03/01/2022	20/01/2022	11/04/2022	25/04/2022	29/04/2022	29/04/2022	04/05/2022	05/05/2022	05/05/2022	05/05/2022	10/05/2022	13/05/2022	19/05/2022
A26	07/02/2022	24/02/2022	16/05/2022	30/05/2022	03/06/2022	03/06/2022	08/06/2022	10/06/2022	10/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022

	Deadline for Submission (*)	Start date (^)	CAT (Co) Rapporteur ARs	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CAT and CHMP (**)	Early draft LOQ (for Peer review tele-conference) (#)	PRAC outcome	Updated PRAC Rapporteur AR	Peer review tele-conference (TC)	Draft LoQ	CAT List of Questions (LoQ) or draft Opinion	CHMP Opinion (~)
A27	07/03/2022	24/03/2022	13/06/2022	27/06/2022	01/07/2022	01/07/2022	06/07/2022	07/07/2022	07/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
A28													
A29	02/05/2022	19/05/2022	08/08/2022	22/08/2022	26/08/2022	26/08/2022	31/08/2022	01/09/2022	01/09/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
A30	30/05/2022	16/06/2022	05/09/2022	19/09/2022	23/09/2022	23/09/2022	28/09/2022	29/09/2022	29/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
A31	27/06/2022	14/07/2022	03/10/2022	17/10/2022	21/10/2022	21/10/2022	26/10/2022	27/10/2022	27/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
A32	01/08/2022	18/08/2022	07/11/2022	21/11/2022	25/11/2022	25/11/2022	30/11/2022	01/12/2022	01/12/2022	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	06/01/2023	06/01/2023	11/01/2023	12/01/2023	12/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
A34	10/10/2022	27/10/2022	16/01/2023	30/01/2023	03/02/2023	03/02/2023	08/02/2023	09/02/2023	09/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
A35	14/11/2022	01/12/2022	20/02/2023	06/03/2023	10/03/2023	10/03/2023	15/03/2023	16/03/2023	16/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
A36	28/11/2022	29/12/2022	20/03/2023	30/03/2023	05/04/2023	05/04/2023	12/04/2023	14/04/2023	14/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
A37	05/01/2023	24/01/2023	17/04/2023	02/05/2023	05/05/2023	05/05/2023	11/05/2023	12/05/2023	12/05/2023	12/05/2023	12/05/2023	17/05/2023	25/05/2023
A38	06/02/2023	23/02/2023	15/05/2023	30/05/2023	02/06/2023	02/06/2023	07/06/2023	08/06/2023	08/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
A39	06/03/2023	23/03/2023	12/06/2023	26/06/2023	30/06/2023	30/06/2023	05/07/2023	06/07/2023	06/07/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
A40													
A41	26/04/2023	18/05/2023	07/08/2023	21/08/2023	25/08/2023	25/08/2023	30/08/2023	31/08/2023	31/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
A42	26/05/2023	15/06/2023	04/09/2023	18/09/2023	22/09/2023	22/09/2023	27/09/2023	28/09/2023	28/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
A43	21/06/2023	10/07/2023	02/10/2023	16/10/2023	20/10/2023	20/10/2023	25/10/2023	26/10/2023	26/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
A44	31/07/2023	17/08/2023	06/11/2023	20/11/2023	24/11/2023	24/11/2023	29/11/2023	30/11/2023	30/11/2023	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	05/01/2024	05/01/2024	10/01/2024	11/01/2024	11/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
A46	09/10/2023	26/10/2023	15/01/2024	29/01/2024	02/02/2024	02/02/2024	07/02/2024	08/02/2024	08/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
A47	06/11/2023	23/11/2023	12/02/2024	26/02/2024	01/03/2024	01/03/2024	06/03/2024	07/03/2024	07/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
A48	27/11/2023	28/12/2023	18/03/2024	02/04/2024	05/04/2024	05/04/2024	10/04/2024	11/04/2024	11/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024
A49	15/01/2024	01/02/2024	22/04/2024	06/05/2024	08/05/2024	08/05/2024	15/05/2024	16/05/2024	16/05/2024	16/05/2024	21/05/2024	24/05/2024	30/05/2024
A50	12/02/2024	29/02/2024	21/05/2024	03/06/2024	07/06/2024	07/06/2024	12/06/2024	13/06/2024	13/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
A51	11/03/2024	28/03/2024	17/06/2024	01/07/2024	05/07/2024	05/07/2024	10/07/2024	11/07/2024	11/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
A52													
A53	30/04/2024	23/05/2024	12/08/2024	26/08/2024	30/08/2024	30/08/2024	04/09/2024	05/09/2024	05/09/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
A54	03/06/2024	20/06/2024	09/09/2024	23/09/2024	27/09/2024	27/09/2024	02/10/2024	03/10/2024	03/10/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024

	Deadline for Submission (*)	Start date (^)	CAT (Co) Rapporteur ARs	PRAC Rapporteur AR	Comments from PRAC (**)	Comments from CAT and CHMP (**)	Early draft LOQ (for Peer review tele-conference) (#)	PRAC outcome	Updated PRAC Rapporteur AR	Peer review telecon-ference (TC)	Draft LoQ	CAT List of Questions (LoQ) or draft Opinion	CHMP Opinion (~)
A55	01/07/2024	18/07/2024	07/10/2024	21/10/2024	25/10/2024	25/10/2024	30/10/2024	31/10/2024	31/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
A56	29/07/2024	15/08/2024	04/11/2024	18/11/2024	22/11/2024	22/11/2024	27/11/2024	28/11/2024	28/11/2024	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.

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

(#) Peer review is a process by which other members of the CAT review the (Co) Rapporteurs' scientific evaluation, as well as the validity of the scientific/regulatory conclusions reached. It applies during the initial phase of the assessment of a new Marketing Authorisation Application (MAA).

(~) 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)

30-day timetable after clock-stop for responses[#]

	Deadline for Submission (*)	Restart	CAT and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC, CAT and CHMP (**)	Updated CAT and PRAC Rapporteurs JAR (~)	CAT draft Opinion	CHMP Opinion
B1	23/12/2019	26/12/2019	09/01/2020	15/01/2020	20/01/2020	24/01/2020	30/01/2020
B2	22/01/2020	23/01/2020	06/02/2020	12/02/2020	17/02/2020	21/02/2020	27/02/2020
B3	19/02/2020	20/02/2020	05/03/2020	11/03/2020	16/03/2020	20/03/2020	26/03/2020
B4	25/03/2020	26/03/2020	08/04/2020	15/04/2020	20/04/2020	24/04/2020	30/04/2020
B5	20/04/2020	21/04/2020	07/05/2020	13/05/2020	15/05/2020	20/05/2020	28/05/2020
B6	20/05/2020	21/05/2020	04/06/2020	10/06/2020	15/06/2020	19/06/2020	25/06/2020
B7	17/06/2020	18/06/2020	02/07/2020	08/07/2020	13/07/2020	17/07/2020	23/07/2020
B8							
B9	12/08/2020	13/08/2020	27/08/2020	02/09/2020	07/09/2020	11/09/2020	17/09/2020
B10	09/09/2020	10/09/2020	24/09/2020	30/09/2020	05/10/2020	09/10/2020	15/10/2020
B11	07/10/2020	08/10/2020	22/10/2020	28/10/2020	03/11/2020	06/11/2020	12/11/2020
B12	04/11/2020	05/11/2020	19/11/2020	25/11/2020	30/11/2020	04/12/2020	10/12/2020
B13	23/12/2020	24/12/2020	07/01/2021	13/01/2021	18/01/2021	22/01/2021	28/01/2021
B14	20/01/2021	21/01/2021	04/02/2021	10/02/2021	15/02/2021	19/02/2021	25/02/2021
B15	17/02/2021	18/02/2021	04/03/2021	10/03/2021	15/03/2021	19/03/2021	25/03/2021
B16	17/03/2021	18/03/2021	31/03/2021	07/04/2021	12/04/2021	16/04/2021	22/04/2021
B17	12/04/2021	13/04/2021	29/04/2021	05/05/2021	07/05/2021	12/05/2021	20/05/2021
B18	19/05/2021	20/05/2021	03/06/2021	09/06/2021	14/06/2021	18/06/2021	24/06/2021
B19	16/06/2021	17/06/2021	01/07/2021	07/07/2021	12/07/2021	16/07/2021	22/07/2021
B20							
B21	11/08/2021	12/08/2021	26/08/2021	01/09/2021	06/09/2021	10/09/2021	16/09/2021
B22	08/09/2021	09/09/2021	23/09/2021	29/09/2021	04/10/2021	08/10/2021	14/10/2021
B23	06/10/2021	07/10/2021	21/10/2021	27/10/2021	29/10/2021	05/11/2021	11/11/2021
B24	10/11/2021	11/11/2021	25/11/2021	01/12/2021	06/12/2021	10/12/2021	16/12/2021
B25	22/12/2021	23/12/2021	06/01/2022	12/01/2022	17/01/2022	21/01/2022	27/01/2022
B26	19/01/2022	20/01/2022	03/02/2022	09/02/2022	14/02/2022	18/02/2022	24/02/2022
B27	16/02/2022	17/02/2022	03/03/2022	09/03/2022	14/03/2022	18/03/2022	24/03/2022
B28	14/03/2022	15/03/2022	31/03/2022	06/04/2022	08/04/2022	13/04/2022	22/04/2022
B29	13/04/2022	14/04/2022	28/04/2022	04/05/2022	10/05/2022	13/05/2022	19/05/2022
B30	18/05/2022	19/05/2022	02/06/2022	08/06/2022	13/06/2022	17/06/2022	23/06/2022
B31	15/06/2022	16/06/2022	30/06/2022	06/07/2022	11/07/2022	15/07/2022	21/07/2022
B32							
B33	10/08/2022	11/08/2022	25/08/2022	31/08/2022	05/09/2022	09/09/2022	15/09/2022
B34	07/09/2022	08/09/2022	22/09/2022	28/09/2022	03/10/2022	07/10/2022	13/10/2022
B35	05/10/2022	06/10/2022	20/10/2022	26/10/2022	28/10/2022	04/11/2022	10/11/2022
B36	09/11/2022	10/11/2022	24/11/2022	30/11/2022	05/12/2022	09/12/2022	15/12/2022
B37	21/12/2022	22/12/2022	05/01/2023	11/01/2023	16/01/2023	20/01/2023	26/01/2023
B38	18/01/2023	19/01/2023	02/02/2023	08/02/2023	13/02/2023	17/02/2023	23/02/2023
B39	22/02/2023	23/02/2023	09/03/2023	15/03/2023	20/03/2023	24/03/2023	30/03/2023
B40	22/03/2023	23/03/2023	05/04/2023	12/04/2023	17/04/2023	21/04/2023	26/04/2023
B41	17/04/2023	18/04/2023	04/05/2023	10/05/2023	12/05/2023	17/05/2023	25/05/2023
B42	17/05/2023	18/05/2023	01/06/2023	07/06/2023	12/06/2023	16/06/2023	22/06/2023
B43	14/06/2023	15/06/2023	29/06/2023	05/07/2023	10/07/2023	14/07/2023	20/07/2023

	Deadline for Submission (*)	Restart	CAT and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC, CAT and CHMP (**)	Updated CAT and PRAC Rapporteurs JAR (~)	CAT draft Opinion	CHMP Opinion
B44							
B45	09/08/2023	10/08/2023	24/08/2023	30/08/2023	04/09/2023	08/09/2023	14/09/2023
B46	06/09/2023	07/09/2023	21/09/2023	27/09/2023	02/10/2023	06/10/2023	12/10/2023
B47	29/09/2023	02/10/2023	19/10/2023	25/10/2023	27/10/2023	31/10/2023	09/11/2023
B48	08/11/2023	09/11/2023	23/11/2023	29/11/2023	04/12/2023	08/12/2023	14/12/2023
B49	20/12/2023	21/12/2023	04/01/2024	10/01/2024	15/01/2024	19/01/2024	25/01/2024
B50	17/01/2024	18/01/2024	01/02/2024	07/02/2024	12/02/2024	16/02/2024	22/02/2024
B51	14/02/2024	15/02/2024	29/02/2024	06/03/2024	11/03/2024	15/03/2024	21/03/2024
B52	20/03/2024	21/03/2024	04/04/2024	10/04/2024	15/04/2024	19/04/2024	25/04/2024
B53	24/04/2024	25/04/2024	08/05/2024	15/05/2024	21/05/2024	24/05/2024	30/05/2024
B54	22/05/2024	23/05/2024	06/06/2024	12/06/2024	17/06/2024	21/06/2024	27/06/2024
B55	19/06/2024	20/06/2024	04/07/2024	10/07/2024	15/07/2024	19/07/2024	25/07/2024
B56							
B57	14/08/2024	15/08/2024	29/08/2024	04/09/2024	09/09/2024	13/09/2024	19/09/2024
B58	11/09/2024	12/09/2024	26/09/2024	02/10/2024	07/10/2024	11/10/2024	17/10/2024
B59	09/10/2024	10/10/2024	24/10/2024	30/10/2024	04/11/2024	08/11/2024	14/11/2024
B60	06/11/2024	07/11/2024	21/11/2024	27/11/2024	02/12/2024	06/12/2024	12/12/2024

(#) In case a longer timetable (60 days) is needed, the application is reverted to a regular (no longer accelerated) timetable. This is also the case if a List of Outstanding Issues is adopted at the end of the 30-day assessment of the responses to the List of Questions and additional assessment rounds are 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.

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

(~) A PRAC discussion is not foreseen for a 30-day timetable; PRAC member comments are reflected in the updated PRAC Rapporteur AR.