



17 December 2020
EMA/824993/2015 Rev.4
Human Medicines

The timetables in this document may be subject to revision

Initial (Full) Marketing Authorisation application assessment timetables Advanced therapy medicinal product (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 \(30-day timetable after immediate responses\)](#)

[Assessment of Outstanding Issues following Oral Explanation \(30-day timetable\)](#)

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)

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

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

	Deadline for Submission (*)	Restart	CAT and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC (**)	Comments from CAT and CHMP (**)	Updated PRAC Rapporteur AR	PRAC outcome (#)	Updated CAT (and PRAC) Rapporteurs JAR (^)	CAT List of Outstanding Issues (LoOI) or draft Opinion	CHMP Opinion (~)
B25	20/12/2021	21/12/2021	25/01/2022	04/02/2022	08/02/2022	10/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022
B26	17/01/2022	18/01/2022	22/02/2022	04/03/2022	08/03/2022	10/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
B27	11/02/2022	13/02/2022	22/03/2022	01/04/2022	05/04/2022	07/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
B28	14/03/2022	15/03/2022	19/04/2022	29/04/2022	03/05/2022	05/05/2022	05/05/2022	06/05/2022	13/05/2022	19/05/2022
B29	13/04/2022	19/04/2022	24/05/2022	03/06/2022	07/06/2022	10/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
B30	16/05/2022	17/05/2022	21/06/2022	01/07/2022	05/07/2022	07/07/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
B31										
B32	11/07/2022	12/07/2022	16/08/2022	26/08/2022	30/08/2022	01/09/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
B33	08/08/2022	09/08/2022	13/09/2022	23/09/2022	27/09/2022	29/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
B34	05/09/2022	06/09/2022	11/10/2022	21/10/2022	25/10/2022	27/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
B35	10/10/2022	11/10/2022	15/11/2022	25/11/2022	29/11/2022	01/12/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
B36	21/11/2022	22/11/2022	22/12/2022	06/01/2023	10/01/2023	12/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
B37	19/12/2022	20/12/2022	24/01/2023	03/02/2023	07/02/2023	09/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
B38	23/01/2023	24/01/2023	28/02/2023	10/03/2023	14/03/2023	16/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
B39	20/02/2023	21/02/2023	28/03/2023	05/04/2023	11/04/2023	14/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
B40	17/03/2023	19/03/2023	25/04/2023	05/05/2023	08/05/2023	11/05/2023	11/05/2023	12/05/2023	17/05/2023	25/05/2023
B41	17/04/2023	18/04/2023	23/05/2023	02/06/2023	06/06/2023	08/06/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
B42	15/05/2023	16/05/2023	20/06/2023	30/06/2023	04/07/2023	06/07/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
B43										
B44	10/07/2023	11/07/2023	14/08/2023	25/08/2023	29/08/2023	31/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
B45	07/08/2023	08/08/2023	12/09/2023	22/09/2023	26/09/2023	28/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
B46	01/09/2023	02/09/2023	10/10/2023	20/10/2023	24/10/2023	26/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
B47	09/10/2023	10/10/2023	14/11/2023	24/11/2023	28/11/2023	30/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
B48	20/11/2023	21/11/2023	21/12/2023	05/01/2024	09/01/2024	11/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
B49	18/12/2023	19/12/2023	23/01/2024	02/02/2024	06/02/2024	08/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
B50	15/01/2024	16/01/2024	20/02/2024	01/03/2024	05/03/2024	07/03/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
B51	19/02/2024	20/02/2024	26/03/2024	05/04/2024	09/04/2024	11/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024

	Deadline for Submission (*)	Restart	CAT and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC (**)	Comments from CAT and CHMP (**)	Updated PRAC Rapporteur AR	PRAC outcome (#)	Updated CAT (and PRAC) Rapporteurs JAR (^)	CAT List of Outstanding Issues (LoOI) or draft Opinion	CHMP Opinion (~)
B52	25/03/2024	26/03/2024	30/04/2024	08/05/2024	14/05/2024	16/05/2024	16/05/2024	17/05/2024	24/05/2024	30/05/2024
B53	22/04/2024	23/04/2024	28/05/2024	07/06/2024	11/06/2024	13/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
B54	17/05/2024	21/05/2024	25/06/2024	05/07/2024	09/07/2024	11/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
B55										
B56	15/07/2024	16/07/2024	20/08/2024	30/08/2024	03/09/2024	05/09/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
B57	12/08/2024	13/08/2024	17/09/2024	27/09/2024	01/10/2024	03/10/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
B58	09/09/2024	10/09/2024	15/10/2024	25/10/2024	29/10/2024	31/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
B59	07/10/2024	08/10/2024	12/11/2024	22/11/2024	26/11/2024	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.

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

(#) The PRAC outcome is captured in the subsequent PRAC Rapporteur updated assessment report.

(^) This assessment report incorporates the PRAC Rapporteur updated assessment report circulated earlier at the conclusion of the PRAC meeting.

(~) 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 and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC, CAT and CHMP (**)	Updated CAT and PRAC Rapporteurs JAR (~)	CAT draft Opinion	CHMP Opinion
C1	23/12/2019	26/12/2019	09/01/2020	15/01/2020	20/01/2020	24/01/2020	30/01/2020
C2	22/01/2020	23/01/2020	06/02/2020	12/02/2020	17/02/2020	21/02/2020	27/02/2020
C3	19/02/2020	20/02/2020	05/03/2020	11/03/2020	16/03/2020	20/03/2020	26/03/2020
C4	25/03/2020	26/03/2020	08/04/2020	15/04/2020	20/04/2020	24/04/2020	30/04/2020
C5	20/04/2020	21/04/2020	07/05/2020	13/05/2020	15/05/2020	20/05/2020	28/05/2020
C6	20/05/2020	21/05/2020	04/06/2020	10/06/2020	15/06/2020	19/06/2020	25/06/2020
C7	17/06/2020	18/06/2020	02/07/2020	08/07/2020	13/07/2020	17/07/2020	23/07/2020
C8							
C9	12/08/2020	13/08/2020	27/08/2020	02/09/2020	07/09/2020	11/09/2020	17/09/2020
C10	09/09/2020	10/09/2020	24/09/2020	30/09/2020	05/10/2020	09/10/2020	15/10/2020
C11	07/10/2020	08/10/2020	22/10/2020	28/10/2020	03/11/2020	06/11/2020	12/11/2020
C12	04/11/2020	05/11/2020	19/11/2020	25/11/2020	30/11/2020	04/12/2020	10/12/2020
C13	23/12/2020	24/12/2020	07/01/2021	13/01/2021	18/01/2021	22/01/2021	28/01/2021
C14	20/01/2021	21/01/2021	04/02/2021	10/02/2021	15/02/2021	19/02/2021	25/02/2021
C15	17/02/2021	18/02/2021	04/03/2021	10/03/2021	15/03/2021	19/03/2021	25/03/2021
C16	17/03/2021	18/03/2021	31/03/2021	07/04/2021	12/04/2021	16/04/2021	22/04/2021
C17	12/04/2021	13/04/2021	29/04/2021	05/05/2021	07/05/2021	12/05/2021	20/05/2021
C18	19/05/2021	20/05/2021	03/06/2021	09/06/2021	14/06/2021	18/06/2021	24/06/2021
C19	16/06/2021	17/06/2021	01/07/2021	07/07/2021	12/07/2021	16/07/2021	22/07/2021
C20							
C21	11/08/2021	12/08/2021	26/08/2021	01/09/2021	06/09/2021	10/09/2021	16/09/2021
C22	08/09/2021	09/09/2021	23/09/2021	29/09/2021	04/10/2021	08/10/2021	14/10/2021
C23	06/10/2021	07/10/2021	21/10/2021	27/10/2021	29/10/2021	05/11/2021	11/11/2021
C24	10/11/2021	11/11/2021	25/11/2021	01/12/2021	06/12/2021	10/12/2021	16/12/2021
C25	22/12/2021	23/12/2021	06/01/2022	12/01/2022	17/01/2022	21/01/2022	27/01/2022
C26	19/01/2022	20/01/2022	03/02/2022	09/02/2022	14/02/2022	18/02/2022	24/02/2022
C27	16/02/2022	17/02/2022	03/03/2022	09/03/2022	14/03/2022	18/03/2022	24/03/2022
C28	14/03/2022	15/03/2022	31/03/2022	06/04/2022	08/04/2022	13/04/2022	22/04/2022
C29	13/04/2022	14/04/2022	28/04/2022	04/05/2022	10/05/2022	13/05/2022	19/05/2022
C30	18/05/2022	19/05/2022	02/06/2022	08/06/2022	13/06/2022	17/06/2022	23/06/2022
C31	15/06/2022	16/06/2022	30/06/2022	06/07/2022	11/07/2022	15/07/2022	21/07/2022
C32							
C33	10/08/2022	11/08/2022	25/08/2022	31/08/2022	05/09/2022	09/09/2022	15/09/2022
C34	07/09/2022	08/09/2022	22/09/2022	28/09/2022	03/10/2022	07/10/2022	13/10/2022
C35	05/10/2022	06/10/2022	20/10/2022	26/10/2022	28/10/2022	04/11/2022	10/11/2022
C36	09/11/2022	10/11/2022	24/11/2022	30/11/2022	05/12/2022	09/12/2022	15/12/2022
C37	21/12/2022	22/12/2022	05/01/2023	11/01/2023	16/01/2023	20/01/2023	26/01/2023
C38	18/01/2023	19/01/2023	02/02/2023	08/02/2023	13/02/2023	17/02/2023	23/02/2023
C39	22/02/2023	23/02/2023	09/03/2023	15/03/2023	20/03/2023	24/03/2023	30/03/2023
C40	22/03/2023	23/03/2023	05/04/2023	12/04/2023	17/04/2023	21/04/2023	26/04/2023
C41	17/04/2023	18/04/2023	04/05/2023	10/05/2023	12/05/2023	17/05/2023	25/05/2023
C42	17/05/2023	18/05/2023	01/06/2023	07/06/2023	12/06/2023	16/06/2023	22/06/2023
C43	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
C44							
C45	09/08/2023	10/08/2023	24/08/2023	30/08/2023	04/09/2023	08/09/2023	14/09/2023
C46	06/09/2023	07/09/2023	21/09/2023	27/09/2023	02/10/2023	06/10/2023	12/10/2023
C47	29/09/2023	02/10/2023	19/10/2023	25/10/2023	27/10/2023	31/10/2023	09/11/2023
C48	08/11/2023	09/11/2023	23/11/2023	29/11/2023	04/12/2023	08/12/2023	14/12/2023
C49	20/12/2023	21/12/2023	04/01/2024	10/01/2024	15/01/2024	19/01/2024	25/01/2024
C50	17/01/2024	18/01/2024	01/02/2024	07/02/2024	12/02/2024	16/02/2024	22/02/2024
C51	14/02/2024	15/02/2024	29/02/2024	06/03/2024	11/03/2024	15/03/2024	21/03/2024
C52	20/03/2024	21/03/2024	04/04/2024	10/04/2024	15/04/2024	19/04/2024	25/04/2024
C53	24/04/2024	25/04/2024	08/05/2024	15/05/2024	21/05/2024	24/05/2024	30/05/2024
C54	22/05/2024	23/05/2024	06/06/2024	12/06/2024	17/06/2024	21/06/2024	27/06/2024
C55	19/06/2024	20/06/2024	04/07/2024	10/07/2024	15/07/2024	19/07/2024	25/07/2024
C56							
C57	14/08/2024	15/08/2024	29/08/2024	04/09/2024	09/09/2024	13/09/2024	19/09/2024
C58	11/09/2024	12/09/2024	26/09/2024	02/10/2024	07/10/2024	11/10/2024	17/10/2024
C59	09/10/2024	10/10/2024	24/10/2024	30/10/2024	04/11/2024	08/11/2024	14/11/2024
C60	06/11/2024	07/11/2024	21/11/2024	27/11/2024	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.

(**) 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.

Assessment of responses to List of Outstanding Issues (LoOI)

30-day timetable after immediate 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
D1	23/12/2019	27/12/2019	14/01/2020	17/01/2020	20/01/2020	24/01/2020	30/01/2020
D2	30/01/2020	31/01/2020	11/02/2020	14/02/2020	17/02/2020	21/02/2020	27/02/2020
D3	27/02/2020	28/02/2020	10/03/2020	13/03/2020	16/03/2020	20/03/2020	26/03/2020
D4	02/04/2020	03/04/2020	14/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
D5	28/04/2020	29/04/2020	11/05/2020	13/05/2020	15/05/2020	20/05/2020	28/05/2020
D6	28/05/2020	29/05/2020	09/06/2020	12/06/2020	15/06/2020	19/06/2020	25/06/2020
D7	25/06/2020	26/06/2020	07/07/2020	10/07/2020	13/07/2020	17/07/2020	23/07/2020
D8							
D9	20/08/2020	21/08/2020	01/09/2020	04/09/2020	07/09/2020	11/09/2020	17/09/2020
D10	17/09/2020	18/09/2020	29/09/2020	02/10/2020	05/10/2020	09/10/2020	15/10/2020
D11	15/10/2020	16/10/2020	27/10/2020	30/10/2020	03/11/2020	06/11/2020	12/11/2020
D12	12/11/2020	13/11/2020	24/11/2020	27/11/2020	30/11/2020	04/12/2020	10/12/2020
D13	23/12/2020	01/01/2021	12/01/2021	15/01/2021	18/01/2021	22/01/2021	28/01/2021
D14	28/01/2021	29/01/2021	09/02/2021	12/02/2021	15/02/2021	19/02/2021	25/02/2021
D15	25/02/2021	26/02/2021	09/03/2021	12/03/2021	15/03/2021	19/03/2021	25/03/2021
D16	25/03/2021	26/03/2021	06/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
D17	20/04/2021	21/04/2021	02/05/2021	05/05/2021	07/05/2021	12/05/2021	20/05/2021
D18	27/05/2021	28/05/2021	08/06/2021	11/06/2021	14/06/2021	18/06/2021	24/06/2021
D19	24/06/2021	25/06/2021	06/07/2021	09/07/2021	12/07/2021	16/07/2021	22/07/2021
D20							
D21	19/08/2021	20/08/2021	31/08/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
D22	16/09/2021	17/09/2021	28/09/2021	01/10/2021	04/10/2021	08/10/2021	14/10/2021
D23	14/10/2021	15/10/2021	26/10/2021	29/10/2021	29/10/2021	05/11/2021	11/11/2021
D24	18/11/2021	19/11/2021	30/11/2021	03/12/2021	06/12/2021	10/12/2021	16/12/2021
D25	21/12/2021	23/12/2021	11/01/2022	14/01/2022	17/01/2022	21/01/2022	27/01/2022
D26	27/01/2022	28/01/2022	08/02/2022	11/02/2022	14/02/2022	18/02/2022	24/02/2022
D27	24/02/2022	25/02/2022	08/03/2022	11/03/2022	14/03/2022	18/03/2022	24/03/2022
D28	22/03/2022	23/03/2022	04/04/2022	06/04/2022	08/04/2022	13/04/2022	22/04/2022
D29	21/04/2022	22/04/2022	03/05/2022	06/05/2022	10/05/2022	13/05/2022	19/05/2022
D30	20/05/2022	23/05/2022	07/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
D31	23/06/2022	24/06/2022	05/07/2022	08/07/2022	11/07/2022	15/07/2022	21/07/2022
D32							
D33	10/08/2022	11/08/2022	30/08/2022	02/09/2022	05/09/2022	09/09/2022	15/09/2022
D34	15/09/2022	16/09/2022	27/09/2022	30/09/2022	03/10/2022	07/10/2022	13/10/2022
D35	13/10/2022	14/10/2022	25/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
D36	11/11/2022	14/11/2022	29/11/2022	02/12/2022	05/12/2022	09/12/2022	15/12/2022
D37	21/12/2022	22/12/2022	10/01/2023	13/01/2023	16/01/2023	20/01/2023	26/01/2023
D38	26/01/2023	27/01/2023	07/02/2023	10/02/2023	13/02/2023	17/02/2023	23/02/2023
D39	24/02/2023	27/02/2023	14/03/2023	17/03/2023	20/03/2023	24/03/2023	30/03/2023

	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
D40	30/03/2023	31/03/2023	11/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
D41	25/04/2023	26/04/2023	08/05/2023	10/05/2023	12/05/2023	17/05/2023	25/05/2023
D42	25/05/2023	26/05/2023	06/06/2023	09/06/2023	12/06/2023	16/06/2023	22/06/2023
D43	22/06/2023	23/06/2023	04/07/2023	07/07/2023	10/07/2023	14/07/2023	20/07/2023
D44							
D45	09/08/2023	10/08/2023	29/08/2023	01/09/2023	04/09/2023	08/09/2023	14/09/2023
D46	14/09/2023	15/09/2023	26/09/2023	29/09/2023	02/10/2023	06/10/2023	12/10/2023
D47	09/10/2023	10/10/2023	20/10/2023	24/10/2023	27/10/2023	31/10/2023	09/11/2023
D48	08/11/2023	09/11/2023	28/11/2023	01/12/2023	04/12/2023	08/12/2023	14/12/2023
D49	20/12/2023	21/12/2023	09/01/2024	12/01/2024	15/01/2024	19/01/2024	25/01/2024
D50	25/01/2024	26/01/2024	06/02/2024	09/02/2024	12/02/2024	16/02/2024	22/02/2024
D51	22/02/2024	23/02/2024	05/03/2024	08/03/2024	11/03/2024	15/03/2024	21/03/2024
D52	22/03/2024	25/03/2024	09/04/2024	12/04/2024	15/04/2024	19/04/2024	25/04/2024
D53	26/04/2024	29/04/2024	14/05/2024	17/05/2024	21/05/2024	24/05/2024	30/05/2024
D54	30/05/2024	31/05/2024	11/06/2024	14/06/2024	17/06/2024	21/06/2024	27/06/2024
D55	27/06/2024	28/06/2024	09/07/2024	12/07/2024	15/07/2024	19/07/2024	25/07/2024
D56							
D57	14/08/2024	15/08/2024	03/09/2024	06/09/2024	09/09/2024	13/09/2024	19/09/2024
D58	19/09/2024	20/09/2024	01/10/2024	04/10/2024	07/10/2024	11/10/2024	17/10/2024
D59	17/10/2024	18/10/2024	29/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
D60	14/11/2024	15/11/2024	26/11/2024	29/11/2024	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.

(**) 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.

Assessment of Outstanding Issues following Oral Explanation

30-day timetable[#]

	Restart	(PRAC and) CAT Rapporteurs Joint AR (JAR) (*)	Comments from (PRAC and) CAT and CHMP on JAR (**)	Updated (PRAC and) CAT Rapporteurs JAR (*)	CAT draft Opinion	CHMP Opinion
E1	27/12/2019	14/01/2020	17/01/2020	20/01/2020	24/01/2020	30/01/2020
E2	31/01/2020	11/02/2020	14/02/2020	17/02/2020	21/02/2020	27/02/2020
E3	28/02/2020	10/03/2020	13/03/2020	16/03/2020	20/03/2020	26/03/2020
E4	30/03/2020	14/04/2020	17/04/2020	20/04/2020	24/04/2020	30/04/2020
E5	29/04/2020	11/05/2020	13/05/2020	15/05/2020	20/05/2020	28/05/2020
E6	29/05/2020	09/06/2020	12/06/2020	15/06/2020	19/06/2020	25/06/2020
E7	26/06/2020	07/07/2020	10/07/2020	13/07/2020	17/07/2020	23/07/2020
E8						
E9	21/08/2020	01/09/2020	04/09/2020	07/09/2020	17/09/2020	17/09/2020
E10	18/09/2020	29/09/2020	02/10/2020	05/10/2020	09/10/2020	15/10/2020
E11	16/10/2020	27/10/2020	30/10/2020	03/11/2020	06/11/2020	12/11/2020
E12	13/11/2020	24/11/2020	27/11/2020	30/11/2020	04/12/2020	10/12/2020
E13	25/12/2020	12/01/2021	15/01/2021	18/01/2021	22/01/2021	28/01/2021
E14	29/01/2021	09/02/2021	12/02/2021	15/02/2021	19/02/2021	25/02/2021
E15	26/02/2021	09/03/2021	12/03/2021	15/03/2021	19/03/2021	25/03/2021
E16	26/03/2021	06/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
E17	21/04/2021	03/05/2021	05/05/2021	07/05/2021	12/05/2021	20/05/2021
E18	25/05/2021	08/06/2021	11/06/2021	14/06/2021	18/06/2021	24/06/2021
E19	25/06/2021	06/07/2021	09/07/2021	12/07/2021	16/07/2021	22/07/2021
E20						
E21	20/08/2021	31/08/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
E22	17/09/2021	28/09/2021	01/10/2021	04/10/2021	08/10/2021	14/10/2021
E23	15/10/2021	26/10/2021	29/10/2021	29/10/2021	05/11/2021	11/11/2021
E24	15/11/2021	30/11/2021	03/12/2021	06/12/2021	10/12/2021	16/12/2021
E25	23/12/2021	11/01/2022	14/01/2022	17/01/2022	21/01/2022	27/01/2022
E26	28/01/2022	08/02/2022	11/02/2022	14/02/2022	18/02/2022	24/02/2022
E27	25/02/2022	08/03/2022	11/03/2022	14/03/2022	18/03/2022	24/03/2022
E28	23/03/2022	04/04/2022	06/04/2022	08/04/2022	13/04/2022	22/04/2022
E29	22/04/2022	03/05/2022	06/05/2022	10/05/2022	13/05/2022	19/05/2022
E30	23/05/2022	07/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
E31	24/06/2022	05/07/2022	08/07/2022	11/07/2022	15/07/2022	21/07/2022
E32						
E33	11/08/2022	30/08/2022	02/09/2022	05/09/2022	09/09/2022	15/09/2022
E34	16/09/2022	27/09/2022	30/09/2022	03/10/2022	07/10/2022	13/10/2022
E35	14/10/2022	25/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
E36	14/11/2022	29/11/2022	02/12/2022	05/12/2022	09/12/2022	15/12/2022
E37	22/12/2022	10/01/2023	13/01/2023	16/01/2023	20/01/2023	26/01/2023
E38	27/01/2023	07/02/2023	10/02/2023	13/02/2023	17/02/2023	23/02/2023
E39	27/02/2023	14/03/2023	17/03/2023	20/03/2023	24/03/2023	30/03/2023

	Restart	(PRAC and) CAT Rapporteurs Joint AR (JAR) (*)	Comments from (PRAC and) CAT and CHMP on JAR (**)	Updated (PRAC and) CAT Rapporteurs JAR (*)	CAT draft Opinion	CHMP Opinion
E40	31/03/2023	11/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
E41	26/04/2023	08/05/2023	10/05/2023	12/05/2023	17/05/2023	25/05/2023
E42	26/05/2023	06/06/2023	09/06/2023	12/06/2023	16/06/2023	22/06/2023
E43	23/06/2023	04/07/2023	07/07/2023	10/07/2023	14/07/2023	20/07/2023
E44						
E45	10/08/2023	29/08/2023	01/09/2023	04/09/2023	08/09/2023	14/09/2023
E46	15/09/2023	26/09/2023	29/09/2023	02/10/2023	06/10/2023	12/10/2023
E47	10/10/2023	20/10/2023	24/10/2023	27/10/2023	31/10/2023	09/11/2023
E48	09/11/2023	28/11/2023	01/12/2023	04/12/2023	08/12/2023	14/12/2023
E49	21/12/2023	09/01/2024	12/01/2024	15/01/2024	19/01/2024	25/01/2024
E50	26/01/2024	06/02/2024	09/02/2024	12/02/2024	16/02/2024	22/02/2024
E51	23/02/2024	05/03/2024	08/03/2024	11/03/2024	15/03/2024	21/03/2024
E52	25/03/2024	09/04/2024	12/04/2024	15/04/2024	19/04/2024	25/04/2024
E53	29/04/2024	14/05/2024	17/05/2024	21/05/2024	24/05/2024	30/05/2024
E54	31/05/2024	11/06/2024	14/06/2024	17/06/2024	21/06/2024	27/06/2024
E55	28/06/2024	09/07/2024	12/07/2024	15/07/2024	19/07/2024	25/07/2024
E56						
E57	15/08/2024	03/09/2024	06/09/2024	09/09/2024	13/09/2024	19/09/2024
E58	20/09/2024	01/10/2024	04/10/2024	07/10/2024	11/10/2024	17/10/2024
E59	18/10/2024	29/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
E60	15/11/2024	26/11/2024	29/11/2024	02/12/2024	06/12/2024	12/12/2024

(#) This timetable is used when minor issues, most commonly but not exclusively related to the Product Information and the Risk Management Plan, remain after an Oral Explanation.

(*) The involvement of CAT and PRAC Rapporteurs in this assessment phase depends on the nature of the remaining issues and it could be optional for the PRAC Rapporteur.

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