



8 May 2023
EMA/339594/2016 Rev.11
Human Medicines Division

The timetables in this document may be subject to revision

Initial (Full) Marketing Authorisation application accelerated assessment timetables[†]

[Assessment of initial submission \(90-day timetable\)](#)

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

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

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

([†]) This timetable is not applicable to Advanced Therapy Medicinal Products (ATMPs); for these the applicant should refer to the timetable for initial Marketing Authorisation applications for ATMPs.

Assessment of initial submission (90-day timetable)

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

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs (***)	PRAC Rapporteur AR	Comments from PRAC and CHMP Co-Rapporteur assessment (**)(***)	Comments from CHMP (**)	PRAC outcome	Early draft LOQ (for Peer review tele-conference)	Peer review teleconference (TC)	Draft LoQ	List of Questions (LoQ) (~) (#)	Opinion (#)
A25	04/01/2022	21/01/2022	22/03/2022	29/03/2022	01/04/2022	07/04/2022	07/04/2022	08/04/2022	11/04/2022	13/04/2022	20/04/2022	22/04/2022
A26	31/01/2022	17/02/2022	19/04/2022	26/04/2022	29/04/2022	05/05/2022	05/05/2022	06/05/2022	10/05/2022	12/05/2022	17/05/2022	19/05/2022
A27	07/03/2022	24/03/2022	24/05/2022	31/05/2022	03/06/2022	10/06/2022	10/06/2022	10/06/2022	13/06/2022	16/06/2022	21/06/2022	23/06/2022
A28	04/04/2022	21/04/2022	21/06/2022	28/06/2022	01/07/2022	07/07/2022	07/07/2022	08/07/2022	11/07/2022	14/07/2022	19/07/2022	21/07/2022
A29												
A30	30/05/2022	16/06/2022	16/08/2022	23/08/2022	26/08/2022	01/09/2022	01/09/2022	02/09/2022	05/09/2022	08/09/2022	13/09/2022	15/09/2022
A31	27/06/2022	14/07/2022	13/09/2022	20/09/2022	23/09/2022	29/09/2022	29/09/2022	30/09/2022	03/10/2022	06/10/2022	11/10/2022	13/10/2022
A32	25/07/2022	11/08/2022	11/10/2022	18/10/2022	21/10/2022	27/10/2022	27/10/2022	28/10/2022	28/10/2022	03/11/2022	08/11/2022	10/11/2022
A33	29/08/2022	15/09/2022	15/11/2022	22/11/2022	25/11/2022	01/12/2022	01/12/2022	02/12/2022	05/12/2022	08/12/2022	13/12/2022	15/12/2022
A34	10/10/2022	27/10/2022	20/12/2022	03/01/2023	06/01/2023	12/01/2023	12/01/2023	13/01/2023	16/01/2023	19/01/2023	24/01/2023	26/01/2023
A35	07/11/2022	24/11/2022	24/01/2023	31/01/2023	03/02/2023	09/02/2023	09/02/2023	10/02/2023	13/02/2023	16/02/2023	21/02/2023	23/02/2023
A36												
A37	09/01/2023	25/01/2023	28/03/2023	03/04/2023	05/04/2023	14/04/2023	14/04/2023	14/04/2023	14/04/2023	19/04/2023	24/04/2023	26/04/2023
A38	06/02/2023	23/02/2023	25/04/2023	02/05/2023	05/05/2023	12/05/2023	12/05/2023	12/05/2023	15/05/2023	17/05/2023	23/05/2023	25/05/2023
A39	06/03/2023	23/03/2023	23/05/2023	30/05/2023	02/06/2023	08/06/2023	08/06/2023	09/06/2023	12/06/2023	15/06/2023	20/06/2023	22/06/2023
A40	03/04/2023	20/04/2023	20/06/2023	27/06/2023	30/06/2023	06/07/2023	06/07/2023	07/07/2023	10/07/2023	13/07/2023	18/07/2023	20/07/2023
A41												
A42	30/05/2023	15/06/2023	16/08/2023	22/08/2023	25/08/2023	31/08/2023	31/08/2023	01/09/2023	04/09/2023	07/09/2023	12/09/2023	14/09/2023
A43	26/06/2023	13/07/2023	12/09/2023	19/09/2023	22/09/2023	28/09/2023	28/09/2023	29/09/2023	02/10/2023	05/10/2023	10/10/2023	12/10/2023
A44	24/07/2023	10/08/2023	10/10/2023	17/10/2023	20/10/2023	26/10/2023	26/10/2023	27/10/2023	30/10/2023	31/10/2023	07/11/2023	09/11/2023
A45	28/08/2023	14/09/2023	14/11/2023	21/11/2023	24/11/2023	30/11/2023	30/11/2023	01/12/2023	04/12/2023	07/12/2023	12/12/2023	14/12/2023
A46	09/10/2023	26/10/2023	19/12/2023	03/01/2024	05/01/2024	11/01/2024	11/01/2024	12/01/2024	15/01/2024	18/01/2024	23/01/2024	25/01/2024
A47	06/11/2023	23/11/2023	23/01/2024	30/01/2024	02/02/2024	08/02/2024	08/02/2024	09/02/2024	12/02/2024	15/02/2024	20/02/2024	22/02/2024
A48												
A49	08/01/2024	25/01/2024	26/03/2024	02/04/2024	05/04/2024	11/04/2024	11/04/2024	12/04/2024	15/04/2024	18/04/2024	23/04/2024	25/04/2024
A50	12/02/2024	29/02/2024	30/04/2024	06/05/2024	08/05/2024	16/05/2024	16/05/2024	17/05/2024	21/05/2024	23/05/2024	28/05/2024	30/05/2024

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs (***)	PRAC Rapporteur AR	Comments from PRAC and CHMP Co-Rapporteur assessment (**)(***)	Comments from CHMP (**)	PRAC outcome	Early draft LOQ (for Peer review tele-conference)	Peer review teleconference (TC)	Draft LoQ	List of Questions (LoQ) (~) (#)	Opinion (#)
A51	11/03/2024	28/03/2024	28/05/2024	04/06/2024	07/06/2024	07/06/2024	13/06/2024	14/06/2024	17/06/2024	20/06/2024	25/06/2024	27/06/2024
A52	08/04/2024	25/04/2024	25/06/2024	02/07/2024	05/07/2024	11/07/2024	11/07/2024	12/07/2024	15/07/2024	18/07/2024	23/07/2024	25/07/2024
A53												
A54	03/06/2024	20/06/2024	20/08/2024	27/08/2024	30/08/2024	05/09/2024	05/09/2024	06/09/2024	09/09/2024	12/09/2024	17/09/2024	19/09/2024
A55	01/07/2024	18/07/2024	17/09/2024	24/09/2024	27/09/2024	03/10/2024	03/10/2024	04/10/2024	07/10/2024	10/10/2024	15/10/2024	17/10/2024
A56	29/07/2024	15/08/2024	15/10/2024	22/10/2024	25/10/2024	31/10/2024	31/10/2024	31/10/2024	04/11/2024	07/11/2024	12/11/2024	14/11/2024
A57	26/08/2024	12/09/2024	12/11/2024	19/11/2024	22/11/2024	28/11/2024	28/11/2024	29/11/2024	02/12/2024	05/12/2024	10/12/2024	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 CHMP and PRAC members are not made available to Applicants.

(~) The accelerated assessment timetable could be reverted to a regular one at the time of the List of Questions and at the judgement of the CHMP. In such a case, the assessment of the responses to the List of Questions will follow the regular 60-day timetable foreseen for initial Marketing authorisation applications, to which the applicant should refer, and the remainder of this timetable will no longer apply.

(#) A List of Question or an Opinion will be adopted at the end of the first assessment phase. An Opinion is adopted on the last day of the CHMP and concludes the assessment procedure. Alternatively, a List of Questions is adopted on the second day of the CHMP meeting.

(***) The CHMP Co-Rapporteur introduces their assessment into the Rapporteur Day 80 Overview assessment report for non-COVID 19 related applications. The Rapporteur AR and Co-Rapporteur assessment will be both made available to the applicant.

Assessment of responses to List of Questions (LOQ)[†]

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

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
B1	24/01/2020	27/01/2020	13/02/2020	18/02/2020	20/02/2020	25/02/2020	27/02/2020
B2	21/02/2020	24/02/2020	12/03/2020	17/03/2020	19/03/2020	24/03/2020	26/03/2020
B3	27/03/2020	30/03/2020	16/04/2020	21/04/2020	23/04/2020	28/04/2020	30/04/2020
B4	24/04/2020	27/04/2020	14/05/2020	18/05/2020	20/05/2020	26/05/2020	28/05/2020
B5	20/05/2020	25/05/2020	11/06/2020	16/06/2020	18/06/2020	23/06/2020	25/06/2020
B6	19/06/2020	22/06/2020	09/07/2020	14/07/2020	16/07/2020	21/07/2020	23/07/2020
B7							
B8	14/08/2020	17/08/2020	03/09/2020	08/09/2020	10/09/2020	15/09/2020	17/09/2020
B9	11/09/2020	14/09/2020	01/10/2020	06/10/2020	08/10/2020	13/10/2020	15/10/2020
B10	09/10/2020	12/10/2020	29/10/2020	03/11/2020	05/11/2020	10/11/2020	12/11/2020
B11	06/11/2020	09/11/2020	26/11/2020	01/12/2020	03/12/2020	08/12/2020	10/12/2020
B12	23/12/2020	28/12/2020	14/01/2021	19/01/2021	21/01/2021	26/01/2021	28/01/2021
B13	22/01/2021	25/01/2021	11/02/2021	16/02/2021	18/02/2021	23/02/2021	25/02/2021
B14	19/02/2021	22/02/2021	11/03/2021	16/03/2021	18/03/2021	23/03/2021	25/03/2021
B15	19/03/2021	22/03/2021	08/04/2021	13/04/2021	15/04/2021	20/04/2021	22/04/2021
B16	16/04/2021	19/04/2021	06/05/2021	10/05/2021	12/05/2021	18/05/2021	20/05/2021
B17	21/05/2021	24/05/2021	10/06/2021	15/06/2021	17/06/2021	22/06/2021	24/06/2021
B18	18/06/2021	21/06/2021	08/07/2021	13/07/2021	15/07/2021	20/07/2021	22/07/2021
B19							
B20	13/08/2021	16/08/2021	02/09/2021	07/09/2021	09/09/2021	14/09/2021	16/09/2021
B21	10/09/2021	13/09/2021	30/09/2021	05/10/2021	07/10/2021	12/10/2021	14/10/2021
B22	08/10/2021	11/10/2021	28/10/2021	03/11/2021	05/11/2021	09/11/2021	11/11/2021
B23	12/11/2021	15/11/2021	02/12/2021	07/12/2021	09/12/2021	14/12/2021	16/12/2021
B24	22/12/2021	27/12/2021	13/01/2022	18/01/2022	20/01/2022	25/01/2022	27/01/2022
B25	21/01/2022	24/01/2022	10/02/2022	15/02/2022	17/02/2022	22/02/2022	24/02/2022
B26	18/02/2022	21/02/2022	10/03/2022	15/03/2022	17/03/2022	22/03/2022	24/03/2022
B27	18/03/2022	22/03/2022	07/04/2022	11/04/2022	13/04/2022	20/04/2022	22/04/2022
B28	13/04/2022	18/04/2022	05/05/2022	10/05/2022	12/05/2022	17/05/2022	19/05/2022

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
B29	20/05/2022	23/05/2022	09/06/2022	14/06/2022	16/06/2022	21/06/2022	23/06/2022
B30	17/06/2022	20/06/2022	07/07/2022	12/07/2022	14/07/2022	19/07/2022	21/07/2022
B31							
B32	12/08/2022	15/08/2022	01/09/2022	06/09/2022	08/09/2022	13/09/2022	15/09/2022
B33	09/09/2022	12/09/2022	29/09/2022	04/10/2022	06/10/2022	11/10/2022	13/10/2022
B34	07/10/2022	10/10/2022	26/10/2022	28/10/2022	03/11/2022	08/11/2022	10/11/2022
B35	11/11/2022	14/11/2022	01/12/2022	06/12/2022	08/12/2022	13/12/2022	15/12/2022
B36	22/12/2022	26/12/2022	12/01/2023	17/01/2023	19/01/2023	24/01/2023	26/01/2023
B37	20/01/2023	23/01/2023	09/02/2023	14/02/2023	16/02/2023	21/02/2023	23/02/2023
B38	24/02/2023	27/02/2023	16/03/2023	21/03/2023	23/03/2023	28/03/2023	30/03/2023
B39	23/03/2023	26/03/2023	13/04/2023	18/04/2023	20/04/2023	24/04/2023	26/04/2023
B40	21/04/2023	24/04/2023	11/05/2023	16/05/2023	17/05/2023	23/05/2023	25/05/2023
B41	17/05/2023	22/05/2023	08/06/2023	13/06/2023	15/06/2023	20/06/2023	22/06/2023
B42	16/06/2023	19/06/2023	06/07/2023	11/07/2023	13/07/2023	18/07/2023	20/07/2023
B43							
B44	11/08/2023	14/08/2023	31/08/2023	05/09/2023	07/09/2023	12/09/2023	14/09/2023
B45	08/09/2023	11/09/2023	28/09/2023	03/10/2023	05/10/2023	10/10/2023	12/10/2023
B46	06/10/2023	09/10/2023	26/10/2023	30/10/2023	31/10/2023	07/11/2023	09/11/2023
B47	10/11/2023	13/11/2023	30/11/2023	05/12/2023	07/12/2023	12/12/2023	14/12/2023
B48	21/12/2023	25/12/2023	11/01/2024	16/01/2024	18/01/2024	23/01/2024	25/01/2024
B49	19/01/2024	22/01/2024	08/02/2024	13/02/2024	15/02/2024	20/02/2024	22/02/2024
B50	16/02/2024	19/02/2024	07/03/2024	12/03/2024	14/03/2024	19/03/2024	21/03/2024
B51	22/03/2024	25/03/2024	11/04/2024	16/04/2024	18/04/2024	23/04/2024	25/04/2024
B52	26/04/2024	29/04/2024	16/05/2024	21/05/2024	23/05/2024	28/05/2024	30/05/2024
B53	24/05/2024	27/05/2024	13/06/2024	18/06/2024	20/06/2024	25/06/2024	27/06/2024
B54	21/06/2024	24/06/2024	11/07/2024	16/07/2024	18/07/2024	23/07/2024	25/07/2024
B55							
B56	16/08/2024	19/08/2024	05/09/2024	10/09/2024	12/09/2024	17/09/2024	19/09/2024
B57	13/09/2024	16/09/2024	03/10/2024	08/10/2024	10/10/2024	15/10/2024	17/10/2024
B58	11/10/2024	14/10/2024	31/10/2024	05/11/2024	07/11/2024	12/11/2024	14/11/2024
B59	08/11/2024	11/11/2024	28/11/2024	03/12/2024	05/12/2024	10/12/2024	12/12/2024

Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
-----------------------------	---------	--	----------------------------------	---	---	-------------

(→) For the assessment of responses to a List of Questions a 30-day timetable with or without clockstop (immediate responses) could apply depending on the applicant's ability to provide responses within 5 days and the CHMP and PRAC Rapporteur's capacity to assess them with a timeframe shorter than 30 days.

(*) 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.

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

(^) The accelerated assessment timetable could still be reverted to a regular one at the time of the List of Outstanding Issues (LoOI) and at the judgement of the CHMP. In such a case, the assessment of the responses to the LoOI will follow the 60-day timetable foreseen for the responses to the List of Questions for initial Marketing authorisation applications, to which the applicant should refer, and the remainder of this timetable will no longer apply.

(#) List of Questions and Opinion are alternative outcomes adopted on the second or last day of the CHMP meeting, respectively.

Assessment of responses to List of Questions (LOQ)[†]

30-day timetable after immediate responses

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
C1	23/12/2019	31/12/2019	16/01/2020	21/01/2020	23/01/2020	28/01/2020	30/01/2020
C2	03/02/2020	04/02/2020	13/02/2020	18/02/2020	20/02/2020	25/02/2020	27/02/2020
C3	02/03/2020	03/03/2020	12/03/2020	17/03/2020	19/03/2020	24/03/2020	26/03/2020
C4	01/04/2020	02/04/2020	16/04/2020	21/04/2020	23/04/2020	28/04/2020	30/04/2020
C5	04/05/2020	05/05/2020	14/05/2020	18/05/2020	20/05/2020	26/05/2020	28/05/2020
C6	29/05/2020	02/06/2020	11/06/2020	16/06/2020	18/06/2020	23/06/2020	25/06/2020
C7	29/06/2020	30/06/2020	09/07/2020	14/07/2020	16/07/2020	21/07/2020	23/07/2020
C8							
C9	24/08/2020	25/08/2020	03/09/2020	08/09/2020	10/09/2020	15/09/2020	17/09/2020
C10	21/09/2020	22/09/2020	01/10/2020	06/10/2020	08/10/2020	13/10/2020	15/10/2020
C11	19/10/2020	20/10/2020	29/10/2020	03/11/2020	05/11/2020	10/11/2020	12/11/2020
C12	16/11/2020	17/11/2020	26/11/2020	01/12/2020	03/12/2020	08/12/2020	10/12/2020
C13	23/12/2020	29/12/2020	14/01/2021	19/01/2021	21/01/2021	26/01/2021	28/01/2021
C14	01/02/2021	02/02/2021	11/02/2021	16/02/2021	18/02/2021	23/02/2021	25/02/2021
C15	01/03/2021	02/03/2021	11/03/2021	16/03/2021	18/03/2021	23/03/2021	25/03/2021
C16	29/03/2021	30/03/2021	08/04/2021	13/04/2021	15/04/2021	20/04/2021	22/04/2021
C17	26/04/2021	27/04/2021	06/05/2021	10/05/2021	12/05/2021	18/05/2021	20/05/2021
C18	26/05/2021	27/05/2021	10/06/2021	15/06/2021	17/06/2021	22/06/2021	24/06/2021
C19	28/06/2021	29/06/2021	08/07/2021	13/07/2021	15/07/2021	20/07/2021	22/07/2021
C20							
C21	23/08/2021	24/08/2021	02/09/2021	07/09/2021	09/09/2021	14/09/2021	16/09/2021
C22	20/09/2021	21/09/2021	30/09/2021	05/10/2021	07/10/2021	12/10/2021	14/10/2021
C23	18/10/2021	19/10/2021	28/10/2021	03/11/2021	05/11/2021	09/11/2021	11/11/2021
C24	17/11/2021	18/11/2021	02/12/2021	07/12/2021	09/12/2021	14/12/2021	16/12/2021
C25	22/12/2021	27/12/2021	13/01/2022	18/01/2022	20/01/2022	25/01/2022	27/01/2022
C26	31/01/2022	01/02/2022	10/02/2022	15/02/2022	17/02/2022	22/02/2022	24/02/2022
C27	28/02/2022	01/03/2022	10/03/2022	15/03/2022	17/03/2022	22/03/2022	24/03/2022
C28	29/03/2022	30/03/2022	07/04/2022	11/04/2022	13/04/2022	20/04/2022	22/04/2022
C29	25/04/2022	26/04/2022	05/05/2022	10/05/2022	12/05/2022	17/05/2022	19/05/2022
C30	23/05/2022	25/05/2022	09/06/2022	14/06/2022	16/06/2022	21/06/2022	23/06/2022
C31	27/06/2022	28/06/2022	07/07/2022	12/07/2022	14/07/2022	19/07/2022	21/07/2022
C32							
C33	22/08/2022	23/08/2022	01/09/2022	06/09/2022	08/09/2022	13/09/2022	15/09/2022
C34	19/09/2022	20/09/2022	29/09/2022	04/10/2022	06/10/2022	11/10/2022	13/10/2022
C35	17/10/2022	18/10/2022	26/10/2022	28/10/2022	03/11/2022	08/11/2022	10/11/2022
C36	14/11/2022	16/11/2022	01/12/2022	06/12/2022	08/12/2022	13/12/2022	15/12/2022
C37	22/12/2022	26/12/2022	12/01/2023	17/01/2023	19/01/2023	24/01/2023	26/01/2023
C38	30/01/2023	31/01/2023	09/02/2023	14/02/2023	16/02/2023	21/02/2023	23/02/2023
C39	28/02/2023	01/03/2023	16/03/2023	21/03/2023	23/03/2023	28/03/2023	30/03/2023
C40	31/03/2023	03/04/2023	13/04/2023	18/04/2023	20/04/2023	24/04/2023	26/04/2023
C41	28/04/2023	02/05/2023	11/05/2023	16/05/2023	17/05/2023	23/05/2023	25/05/2023
C42	26/05/2023	30/05/2023	08/06/2023	13/06/2023	15/06/2023	20/06/2023	22/06/2023
C43	26/06/2023	27/06/2023	06/07/2023	11/07/2023	13/07/2023	18/07/2023	20/07/2023
C44							
C45	21/08/2023	22/08/2023	31/08/2023	05/09/2023	07/09/2023	12/09/2023	14/09/2023
C46	18/09/2023	19/09/2023	28/09/2023	03/10/2023	05/10/2023	10/10/2023	12/10/2023

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) (^) (#)	Opinion (#)
C47	16/10/2023	17/10/2023	26/10/2023	30/10/2023	31/10/2023	07/11/2023	09/11/2023
C48	14/11/2023	15/11/2023	30/11/2023	05/12/2023	07/12/2023	12/12/2023	14/12/2023
C49	21/12/2023	25/12/2023	11/01/2024	16/01/2024	18/01/2024	23/01/2024	25/01/2024
C50	29/01/2024	30/01/2024	08/02/2024	13/02/2024	15/02/2024	20/02/2024	22/02/2024
C51	26/02/2024	27/02/2024	07/03/2024	12/03/2024	14/03/2024	19/03/2024	21/03/2024
C52	26/03/2024	27/03/2024	11/04/2024	16/04/2024	18/04/2024	23/04/2024	25/04/2024
C53	30/04/2024	01/05/2024	16/05/2024	21/05/2024	23/05/2024	28/05/2024	30/05/2024
C54	03/06/2024	04/06/2024	13/06/2024	18/06/2024	20/06/2024	25/06/2024	27/06/2024
C55	01/07/2024	02/07/2024	11/07/2024	16/07/2024	18/07/2024	23/07/2024	25/07/2024
C56							
C57	26/08/2024	27/08/2024	05/09/2024	10/09/2024	12/09/2024	17/09/2024	19/09/2024
C58	23/09/2024	24/09/2024	03/10/2024	08/10/2024	10/10/2024	15/10/2024	17/10/2024
C59	21/10/2024	22/10/2024	31/10/2024	05/11/2024	07/11/2024	12/11/2024	14/11/2024
C60	18/11/2024	19/11/2024	28/11/2024	03/12/2024	05/12/2024	10/12/2024	12/12/2024

(-) For the assessment of responses to a List of Questions a 30-day timetable with or without clockstop (immediate responses) could apply depending on the applicant's ability to provide responses within 5 days and the CHMP and PRAC Rapporteur's capacity to assess them with a timeframe shorter than 30 days.

(*) 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.

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

(^) The accelerated assessment timetable could still be reverted to a regular one at the time of the List of Outstanding Issues (LoOI) and at the judgement of the CHMP. In such a case, the assessment of the responses to the LoOI will follow the 60-day timetable foreseen for the responses to the List of Questions for initial Marketing authorisation applications, to which the applicant should refer, and the remainder of this timetable will no longer apply.

(#) List of Questions and Opinion are alternative outcomes adopted on the second or last day of the CHMP meeting, respectively.

Assessment of responses to List of Outstanding Issues (LoOI)[†]

30-day timetable after immediate responses

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	Opinion(^)
D1	23/12/2019	01/01/2020	16/01/2020	21/01/2020	23/01/2020	30/01/2020
D2	04/02/2020	05/02/2020	13/02/2020	18/02/2020	20/02/2020	27/02/2020
D3	03/03/2020	04/03/2020	12/03/2020	17/03/2020	19/03/2020	26/03/2020
D4	02/04/2020	03/04/2020	16/04/2020	21/04/2020	23/04/2020	30/04/2020
D5	05/05/2020	06/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
D6	02/06/2020	03/06/2020	11/06/2020	16/06/2020	18/06/2020	25/06/2020
D7	30/06/2020	01/07/2020	09/07/2020	14/07/2020	16/07/2020	23/07/2020
D8						
D9	18/08/2020	19/08/2020	03/09/2020	08/09/2020	10/09/2020	17/09/2020
D10	22/09/2020	23/09/2020	01/10/2020	06/10/2020	08/10/2020	15/10/2020
D11	20/10/2020	21/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
D12	17/11/2020	18/11/2020	26/11/2020	01/12/2020	03/12/2020	10/12/2020
D13	23/12/2020	30/12/2020	14/01/2021	19/01/2021	21/01/2021	28/01/2021
D14	02/02/2021	03/02/2021	11/02/2021	16/02/2021	18/02/2021	25/02/2021
D15	02/03/2021	03/03/2021	11/03/2021	16/03/2021	18/03/2021	25/03/2021
D16	30/03/2021	31/03/2021	08/04/2021	13/04/2021	15/04/2021	22/04/2021
D17	27/04/2021	28/04/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
D18	27/05/2021	28/05/2021	10/06/2021	15/06/2021	17/06/2021	24/06/2021
D19	29/06/2021	30/06/2021	08/07/2021	13/07/2021	15/07/2021	22/07/2021
D20						
D21	17/08/2021	18/08/2021	02/09/2021	07/09/2021	09/09/2021	16/09/2021
D22	21/09/2021	22/09/2021	30/09/2021	05/10/2021	07/10/2021	14/10/2021
D23	19/10/2021	20/10/2021	28/10/2021	03/11/2021	05/11/2021	11/11/2021
D24	18/11/2021	19/11/2021	02/12/2021	07/12/2021	09/12/2021	16/12/2021
D25	22/12/2021	29/12/2021	13/01/2022	18/01/2022	20/01/2022	27/01/2022
D26	01/02/2022	02/02/2022	10/02/2022	15/02/2022	17/02/2022	24/02/2022
D27	01/03/2022	02/03/2022	10/03/2022	15/03/2022	17/03/2022	24/03/2022
D28	30/03/2022	31/03/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
D29	26/04/2022	27/04/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
D30	25/05/2022	27/05/2022	09/06/2022	14/06/2022	16/06/2022	23/06/2022
D31	28/06/2022	29/06/2022	07/07/2022	12/07/2022	14/07/2022	21/07/2022
D32						
D33	16/08/2022	17/08/2022	01/09/2022	06/09/2022	08/09/2022	15/09/2022
D34	20/09/2022	21/09/2022	29/09/2022	04/10/2022	06/10/2022	13/10/2022
D35	18/10/2022	19/10/2022	26/10/2022	28/10/2022	03/11/2022	10/11/2022
D36	16/11/2022	18/11/2022	01/12/2022	06/12/2022	08/12/2022	15/12/2022
D37	22/12/2022	28/12/2022	12/01/2023	17/01/2023	19/01/2023	26/01/2023
D38	31/01/2023	01/02/2023	09/02/2023	14/02/2023	16/02/2023	23/02/2023
D39	28/02/2023	01/03/2023	16/03/2023	21/03/2023	23/03/2023	30/03/2023

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	Opinion(^)
D40	03/04/2023	04/04/2023	13/04/2023	18/04/2023	20/04/2023	26/04/2023
D41	02/05/2023	03/05/2023	11/05/2023	16/05/2023	17/05/2023	25/05/2023
D42	30/05/2023	31/05/2023	08/06/2023	13/06/2023	15/06/2023	22/06/2023
D43	27/06/2023	28/06/2023	06/07/2023	11/07/2023	13/07/2023	20/07/2023
D44						
D45	14/08/2023	16/08/2023	31/08/2023	05/09/2023	07/09/2023	14/09/2023
D46	19/09/2023	20/09/2023	28/09/2023	03/10/2023	05/10/2023	12/10/2023
D47	17/10/2023	18/10/2023	26/10/2023	30/10/2023	31/10/2023	09/11/2023
D48	16/11/2023	17/11/2023	30/11/2023	05/12/2023	07/12/2023	14/12/2023
D49	21/12/2023	27/12/2023	11/01/2024	16/01/2024	18/01/2024	25/01/2024
D50	30/01/2024	31/01/2024	08/02/2024	13/02/2024	15/02/2024	22/02/2024
D51	27/02/2024	28/02/2024	07/03/2024	12/03/2024	14/03/2024	21/03/2024
D52	27/03/2024	29/03/2024	11/04/2024	16/04/2024	18/04/2024	25/04/2024
D53	02/05/2024	03/05/2024	16/05/2024	21/05/2024	23/05/2024	30/05/2024
D54	04/06/2024	05/06/2024	13/06/2024	18/06/2024	20/06/2024	27/06/2024
D55	02/07/2024	03/07/2024	11/07/2024	16/07/2024	18/07/2024	25/07/2024
D56						
D57	20/08/2024	21/08/2024	05/09/2024	10/09/2024	12/09/2024	19/09/2024
D58	24/09/2024	25/09/2024	03/10/2024	08/10/2024	10/10/2024	17/10/2024
D59	22/10/2024	23/10/2024	31/10/2024	05/11/2024	07/11/2024	14/11/2024
D60	19/11/2024	20/11/2024	28/11/2024	03/12/2024	05/12/2024	12/12/2024

(-) For the assessment of responses to a List of Outstanding Issues a 30-day timetable with or without clockstop (immediate responses) could apply depending on the applicant's ability to provide responses within 5 days and the CHMP and PRAC Rapporteur's capacity to assess them with the shorter timeframe.

(*) The Agency strongly recommends submitting the application before the published submission deadline. This is to avoid missing the target start date as a result of a technically invalid eCTD submission, in which case the submission is considered void and it needs to be re-despatched.

(**) Comments from 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.

(^) The accelerated assessment timetable could still be reverted to a regular one at this time through adoption of a second List of Outstanding Issues (LoOI) and at the judgement of the CHMP. In such a case, the assessment of the responses to the 2nd LoOI can only follow the 60-day timetable foreseen for the responses to the List of Outstanding Issues for initial Marketing authorisation applications, to which the applicant should refer.