



15 February 2021
EMA/267769/2016 Rev.2
Human Medicines Division

An agency of the European Union



The timetables in this document may be subject to revision

Paediatric art. 46 submission (Post-Authorisation Measure) - ATMP

Initial submission assessment timetable

[60-day](#)

Responses to Request for Supplementary Information (RSI) assessment timetable

[30-day after clockstop](#)

[30-day after immediate responses](#)

60-day initial submission assessment timetable

	Deadline for Submission (*)	Start date	CAT Rapporteur AR	Comments from CAT and CHMP (~)	Updated CAT Rapporteur AR (#)	CAT conclusion or Request for Supplementary Information	CHMP conclusion (^)
A1	17/11/2020	30/11/2020	04/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
A2	10/12/2020	28/12/2020	01/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
A3	12/01/2021	25/01/2021	01/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
A4	09/02/2021	22/02/2021	29/03/2021	08/04/2021	12/04/2021	16/04/2021	22/04/2021
A5	05/03/2021	20/03/2021	26/04/2021	04/05/2021	07/05/2021	12/05/2021	20/05/2021
A6	13/04/2021	26/04/2021	31/05/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
A7	11/05/2021	24/05/2021	28/06/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
A8	08/06/2021	21/06/2021	26/07/2021	05/08/2021	09/08/2021	13/08/2021	19/08/2021
A9	06/07/2021	19/07/2021	23/08/2021	02/09/2021	06/09/2021	10/09/2021	16/09/2021
A10	03/08/2021	16/08/2021	20/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
A11	31/08/2021	13/09/2021	18/10/2021	26/10/2021	29/10/2021	05/11/2021	11/11/2021
A12	05/10/2021	18/10/2021	22/11/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
A13	16/11/2021	29/11/2021	03/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
A14	14/12/2021	27/12/2021	31/01/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022
A15	11/01/2022	24/01/2022	28/02/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
A16	07/02/2022	19/02/2022	28/03/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
A17	08/03/2022	21/03/2022	25/04/2022	05/05/2022	10/05/2022	13/05/2022	19/05/2022
A18	12/04/2022	25/04/2022	30/05/2022	09/06/2022	13/06/2022	17/06/2022	23/06/2022
A19	10/05/2022	23/05/2022	27/06/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
A20	07/06/2022	20/06/2022	25/07/2022	04/08/2022	08/08/2022	12/08/2022	19/08/2022
A21	05/07/2022	18/07/2022	22/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
A22	02/08/2022	15/08/2022	19/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
A23	30/08/2022	12/09/2022	17/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
A24	04/10/2022	17/10/2022	21/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
A25	15/11/2022	28/11/2022	03/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
A26	13/12/2022	26/12/2022	30/01/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
A27	17/01/2023	30/01/2023	06/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
A28	14/02/2023	27/02/2023	03/04/2023	13/04/2023	17/04/2023	21/04/2023	26/04/2023
A29	10/03/2023	25/03/2023	02/05/2023	11/05/2023	15/05/2023	17/05/2023	25/05/2023
A30	11/04/2023	24/04/2023	30/05/2023	08/06/2023	12/06/2023	16/06/2023	22/06/2023
A31	08/05/2023	22/05/2023	26/06/2023	06/07/2023	10/07/2023	14/07/2023	20/07/2023
A32	06/06/2023	19/06/2023	24/07/2023	03/08/2023	07/08/2023	11/08/2023	17/08/2023
A33	04/07/2023	17/07/2023	21/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
A34	01/08/2023	14/08/2023	18/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
A35	25/08/2023	08/09/2023	16/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
A36	03/10/2023	16/10/2023	20/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
A37	14/11/2023	27/11/2023	03/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
A38	12/12/2023	25/12/2023	29/01/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
A39	09/01/2024	22/01/2024	26/02/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
A40	13/02/2024	26/02/2024	02/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024
A41	19/03/2024	01/04/2024	06/05/2024	16/05/2024	21/05/2024	24/05/2024	30/05/2024
A42	16/04/2024	29/04/2024	03/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024

	Deadline for Submission (*)	Start date	CAT Rapporteur AR	Comments from CAT and CHMP (~)	Updated CAT Rapporteur AR (#)	CAT conclusion or Request for Supplementary Information	CHMP conclusion (^)
A43	14/05/2024	27/05/2024	01/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
A44	11/06/2024	24/06/2024	29/07/2024	08/08/2024	12/08/2024	16/08/2024	22/08/2024
A45	09/07/2024	22/07/2024	26/08/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
A46	06/08/2024	19/08/2024	23/09/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
A47	03/09/2024	16/09/2024	21/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
A48	01/10/2024	14/10/2024	18/11/2024	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 CAT and CHMP members are not made available to Marketing authorisation Holders (MAHs).

(#) An updated AR is optional and dependent on the comments received from CAT and CHMP members which create the need for the update.

(^) Step applicable only in case of CAT final conclusion (not applicable in case a Request for Supplementary Information is adopted by the CAT).

30-day responses (after clockstop) to RSI assessment timetable

	Deadline for Submission (*)	Start date	CAT Rapporteur AR	Comments from CAT and CHMP (~)	Updated CAT Rapporteur AR (#)	CAT conclusion	CHMP conclusion
B1	23/12/2020	24/12/2020	07/01/2021	14/01/2021	18/01/2021	22/01/2021	28/01/2021
B2	20/01/2021	21/01/2021	04/02/2021	11/02/2021	15/02/2021	19/02/2021	25/02/2021
B3	17/02/2021	18/02/2021	04/03/2021	11/03/2021	15/03/2021	19/03/2021	25/03/2021
B4	17/03/2021	18/03/2021	31/03/2021	08/04/2021	12/04/2021	16/04/2021	22/04/2021
B5	12/04/2021	13/04/2021	27/04/2021	04/05/2021	07/05/2021	12/05/2021	20/05/2021
B6	19/05/2021	20/05/2021	03/06/2021	10/06/2021	14/06/2021	18/06/2021	24/06/2021
B7	16/06/2021	17/06/2021	01/07/2021	08/07/2021	12/07/2021	16/07/2021	22/07/2021
B8	14/07/2021	15/07/2021	29/07/2021	05/08/2021	09/08/2021	13/08/2021	19/08/2021
B9	11/08/2021	12/08/2021	26/08/2021	02/09/2021	06/09/2021	10/09/2021	16/09/2021
B10	08/09/2021	09/09/2021	23/09/2021	30/09/2021	04/10/2021	08/10/2021	14/10/2021
B11	06/10/2021	07/10/2021	21/10/2021	27/10/2021	29/10/2021	05/11/2021	11/11/2021
B12	10/11/2021	11/11/2021	25/11/2021	02/12/2021	06/12/2021	10/12/2021	16/12/2021
B13	22/12/2021	23/12/2021	06/01/2022	13/01/2022	17/01/2022	21/01/2022	27/01/2022
B14	19/01/2022	20/01/2022	03/02/2022	10/02/2022	14/02/2022	18/02/2022	24/02/2022
B15	16/02/2022	17/02/2022	03/03/2022	10/03/2022	14/03/2022	18/03/2022	24/03/2022
B16	14/03/2022	15/03/2022	31/03/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
B17	13/04/2022	14/04/2022	28/04/2022	05/05/2022	10/05/2022	13/05/2022	19/05/2022
B18	18/05/2022	19/05/2022	02/06/2022	09/06/2022	13/06/2022	17/06/2022	23/06/2022
B19	15/06/2022	16/06/2022	30/06/2022	07/07/2022	11/07/2022	15/07/2022	21/07/2022
B20	13/07/2022	14/07/2022	28/07/2022	04/08/2022	08/08/2022	12/08/2022	19/08/2022
B21	10/08/2022	11/08/2022	25/08/2022	01/09/2022	05/09/2022	09/09/2022	15/09/2022
B22	07/09/2022	08/09/2022	22/09/2022	29/09/2022	03/10/2022	07/10/2022	13/10/2022
B23	05/10/2022	06/10/2022	20/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
B24	09/11/2022	10/11/2022	24/11/2022	01/12/2022	05/12/2022	09/12/2022	15/12/2022
B25	21/12/2022	22/12/2022	05/01/2023	12/01/2023	16/01/2023	20/01/2023	26/01/2023
B26	18/01/2023	19/01/2023	02/02/2023	09/02/2023	13/02/2023	17/02/2023	23/02/2023
B27	22/02/2023	23/02/2023	09/03/2023	16/03/2023	20/03/2023	24/03/2023	30/03/2023
B28	22/03/2023	23/03/2023	05/04/2023	13/04/2023	17/04/2023	21/04/2023	26/04/2023
B29	17/04/2023	18/04/2023	04/05/2023	11/05/2023	12/05/2023	17/05/2023	25/05/2023
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B32	12/07/2023	13/07/2023	27/07/2023	03/08/2023	07/08/2023	11/08/2023	17/08/2023
B33	09/08/2023	10/08/2023	24/08/2023	31/08/2023	04/09/2023	08/09/2023	14/09/2023
B34	06/09/2023	07/09/2023	21/09/2023	28/09/2023	02/10/2023	06/10/2023	12/10/2023
B35	29/09/2023	02/10/2023	19/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
B36	08/11/2023	09/11/2023	23/11/2023	30/11/2023	04/12/2023	08/12/2023	14/12/2023
B37	20/12/2023	21/12/2023	04/01/2024	11/01/2024	15/01/2024	19/01/2024	25/01/2024
B38	17/01/2024	18/01/2024	01/02/2024	08/02/2024	12/02/2024	16/02/2024	22/02/2024
B39	14/02/2024	15/02/2024	29/02/2024	07/03/2024	11/03/2024	15/03/2024	21/03/2024
B40	20/03/2024	21/03/2024	04/04/2024	11/04/2024	15/04/2024	19/04/2024	25/04/2024
B41	24/04/2024	25/04/2024	08/05/2024	16/05/2024	21/05/2024	24/05/2024	30/05/2024
B42	22/05/2024	23/05/2024	06/06/2024	13/06/2024	17/06/2024	21/06/2024	27/06/2024
B43	19/06/2024	20/06/2024	04/07/2024	11/07/2024	15/07/2024	19/07/2024	25/07/2024
B44	17/07/2024	18/07/2024	01/08/2024	08/08/2024	12/08/2024	16/08/2024	22/08/2024
B45	14/08/2024	15/08/2024	29/08/2024	05/09/2024	09/09/2024	13/09/2024	19/09/2024
B46	11/09/2024	12/09/2024	26/09/2024	03/10/2024	07/10/2024	11/10/2024	17/10/2024
B47	09/10/2024	10/10/2024	24/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
B48	06/11/2024	07/11/2024	21/11/2024	28/11/2024	02/12/2024	06/12/2024	12/12/2024

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30-day immediate responses to RSI assessment timetable

	Deadline for Submission (*)	Start date	CAT Rapporteur AR	Comments from CAT and CHMP (~)	Updated CAT Rapporteur AR (#)	CAT conclusion	CHMP conclusion
C1	23/12/2020	25/12/2020	12/01/2021	15/01/2021	18/01/2021	22/01/2021	28/01/2021
C2	28/01/2021	29/01/2021	09/02/2021	12/02/2021	15/02/2021	19/02/2021	25/02/2021
C3	25/02/2021	26/02/2021	09/03/2021	12/03/2021	15/03/2021	19/03/2021	25/03/2021
C4	25/03/2021	26/03/2021	06/04/2021	09/04/2021	12/04/2021	16/04/2021	22/04/2021
C5	20/04/2021	21/04/2021	30/04/2021	04/05/2021	07/05/2021	12/05/2021	20/05/2021
C6	21/05/2021	25/05/2021	08/06/2021	11/06/2021	14/06/2021	18/06/2021	24/06/2021
C7	24/06/2021	25/06/2021	06/07/2021	09/07/2021	12/07/2021	16/07/2021	22/07/2021
C8	22/07/2021	23/07/2021	03/08/2021	06/08/2021	09/08/2021	13/08/2021	19/08/2021
C9	19/08/2021	20/08/2021	31/08/2021	03/09/2021	06/09/2021	10/09/2021	16/09/2021
C10	16/09/2021	17/09/2021	28/09/2021	01/10/2021	04/10/2021	08/10/2021	14/10/2021
C11	14/10/2021	15/10/2021	21/10/2021	27/10/2021	03/11/2021	05/11/2021	11/11/2021
C12	12/11/2021	15/11/2021	30/11/2021	03/12/2021	06/12/2021	10/12/2021	16/12/2021
C13	22/12/2021	31/12/2021	11/01/2022	14/01/2022	17/01/2022	21/01/2022	27/01/2022
C14	27/01/2022	28/01/2022	08/02/2022	11/02/2022	14/02/2022	18/02/2022	24/02/2022
C15	24/02/2022	25/02/2022	08/03/2022	11/03/2022	14/03/2022	18/03/2022	24/03/2022
C16	22/03/2022	23/03/2022	01/04/2022	05/04/2022	08/04/2022	13/04/2022	22/04/2022
C17	21/04/2022	22/04/2022	03/05/2022	06/05/2022	10/05/2022	13/05/2022	19/05/2022
C18	24/05/2022	27/05/2022	07/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
C19	23/06/2022	24/06/2022	05/07/2022	08/07/2022	11/07/2022	15/07/2022	21/07/2022
C20	21/07/2022	22/07/2022	02/08/2022	05/08/2022	08/08/2022	12/08/2022	19/08/2022
C21	18/08/2022	19/08/2022	30/08/2022	02/09/2022	05/09/2022	09/09/2022	15/09/2022
C22	15/09/2022	16/09/2022	27/09/2022	30/09/2022	03/10/2022	07/10/2022	13/10/2022
C23	13/10/2022	14/10/2022	25/10/2022	28/10/2022	28/10/2022	04/11/2022	10/11/2022
C24	17/11/2022	18/11/2022	29/11/2022	02/12/2022	05/12/2022	09/12/2022	15/12/2022
C25	22/12/2022	30/12/2022	10/01/2023	13/01/2023	16/01/2023	20/01/2023	26/01/2023
C26	26/01/2023	27/01/2023	07/02/2023	10/02/2023	13/02/2023	17/02/2023	23/02/2023
C27	02/03/2023	03/03/2023	14/03/2023	17/03/2023	20/03/2023	24/03/2023	30/03/2023
C28	30/03/2023	31/03/2023	11/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
C29	25/04/2023	26/04/2023	05/05/2023	08/05/2023	12/05/2023	17/05/2023	25/05/2023
C30	25/05/2023	26/05/2023	06/06/2023	09/06/2023	12/06/2023	16/06/2023	22/06/2023
C31	22/06/2023	23/06/2023	04/07/2023	07/07/2023	10/07/2023	14/07/2023	20/07/2023
C32	20/07/2023	21/07/2023	01/08/2023	04/08/2023	07/08/2023	11/08/2023	17/08/2023
C33	17/08/2023	18/08/2023	29/08/2023	01/09/2023	04/09/2023	08/09/2023	14/09/2023
C34	14/09/2023	15/09/2023	26/09/2023	29/09/2023	02/10/2023	06/10/2023	12/10/2023
C35	09/10/2023	10/10/2023	20/10/2023	24/10/2023	27/10/2023	31/10/2023	09/11/2023
C36	16/11/2023	17/11/2023	28/11/2023	01/12/2023	04/12/2023	08/12/2023	14/12/2023
C37	21/12/2023	29/12/2023	09/01/2024	12/01/2024	15/01/2024	19/01/2024	25/01/2024
C38	25/01/2024	26/01/2024	06/02/2024	09/02/2024	12/02/2024	16/02/2024	22/02/2024
C39	22/02/2024	23/02/2024	05/03/2024	08/03/2024	11/03/2024	15/03/2024	21/03/2024
C40	26/03/2024	29/03/2024	09/04/2024	12/04/2024	15/04/2024	19/04/2024	25/04/2024
C41	02/05/2024	03/05/2024	14/05/2024	17/05/2024	21/05/2024	24/05/2024	30/05/2024
C42	30/05/2024	31/05/2024	11/06/2024	14/06/2024	17/06/2024	21/06/2024	27/06/2024
C43	27/06/2024	28/06/2024	09/07/2024	12/07/2024	15/07/2024	19/07/2024	25/07/2024
C44	25/07/2024	26/07/2024	06/08/2024	09/08/2024	12/08/2024	16/08/2024	22/08/2024

	Deadline for Submission (*)	Start date	CAT Rapporteur AR	Comments from CAT and CHMP (~)	Updated CAT Rapporteur AR (#)	CAT conclusion	CHMP conclusion
C45	22/08/2024	23/08/2024	03/09/2024	06/09/2024	09/09/2024	13/09/2024	19/09/2024
C46	19/09/2024	20/09/2024	01/10/2024	04/10/2024	07/10/2024	11/10/2024	17/10/2024
C47	17/10/2024	18/10/2024	29/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
C48	14/11/2024	15/11/2024	26/11/2024	29/11/2024	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 and CHMP members are not made available to Marketing authorisation Holders (MAHs).

(#) An updated AR is optional and dependent on the comments received from CAT and CHMP members which create the need for the update.