



6 July 2018
EMA/267769/2016 Rev.1
Human Medicines Evaluation

[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	15/05/2018	28/05/2018	02/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
A2	12/06/2018	25/06/2018	30/07/2018	09/08/2018	13/08/2018	17/08/2018	23/08/2018
A3	10/07/2018	23/07/2018	28/08/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
A4	07/08/2018	20/08/2018	24/09/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
A5	04/09/2018	17/09/2018	22/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
A6	02/10/2018	15/10/2018	19/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018
A7	20/11/2018	03/12/2018	07/01/2019	17/01/2019	21/01/2019	25/01/2019	25/01/2019
A8	07/12/2018	31/12/2018	04/02/2019	14/02/2019	18/02/2019	22/02/2019	22/02/2019
A9	15/01/2019	28/01/2019	04/03/2019	14/03/2019	18/03/2019	22/03/2019	22/03/2019
A10	08/02/2019	23/02/2019	01/04/2019	09/04/2019	12/04/2019	17/04/2019	17/04/2019
A11	19/03/2019	01/04/2019	06/05/2019	16/05/2019	20/05/2019	24/05/2019	24/05/2019
A12	16/04/2019	29/04/2019	03/06/2019	13/06/2019	17/06/2019	21/06/2019	21/06/2019
A13	14/05/2019	27/05/2019	01/07/2019	11/07/2019	15/07/2019	19/07/2019	19/07/2019
A14	11/06/2019	24/06/2019	29/07/2019	08/08/2019	12/08/2019	16/08/2019	16/08/2019
A15	09/07/2019	22/07/2019	27/08/2019	05/09/2019	09/09/2019	13/09/2019	13/09/2019
A16	06/08/2019	19/08/2019	23/09/2019	03/10/2019	07/10/2019	11/10/2019	11/10/2019
A17	03/09/2019	16/09/2019	21/10/2019	31/10/2019	04/11/2019	08/11/2019	08/11/2019
A18	01/10/2019	14/10/2019	18/11/2019	28/11/2019	02/12/2019	06/12/2019	06/12/2019
A19	19/11/2019	02/12/2019	06/01/2020	16/01/2020	20/01/2020	24/01/2020	24/01/2020
A20	06/12/2019	30/12/2019	03/02/2020	13/02/2020	17/02/2020	21/02/2020	21/02/2020
A21	14/01/2020	27/01/2020	02/03/2020	12/03/2020	16/03/2020	20/03/2020	20/03/2020
A22	18/02/2020	02/03/2020	06/04/2020	16/04/2020	20/04/2020	24/04/2020	24/04/2020
A23	13/03/2020	28/03/2020	04/05/2020	12/05/2020	15/05/2020	20/05/2020	20/05/2020
A24	14/04/2020	27/04/2020	02/06/2020	11/06/2020	15/06/2020	19/06/2020	19/06/2020
A25	12/05/2020	25/05/2020	29/06/2020	09/07/2020	13/07/2020	17/07/2020	17/07/2020
A26	09/06/2020	22/06/2020	27/07/2020	06/08/2020	10/08/2020	14/08/2020	14/08/2020
A27	07/07/2020	20/07/2020	24/08/2020	03/09/2020	07/09/2020	11/09/2020	11/09/2020
A28	04/08/2020	17/08/2020	21/09/2020	01/10/2020	05/10/2020	09/10/2020	09/10/2020
A29	01/09/2020	14/09/2020	19/10/2020	29/10/2020	03/11/2020	06/11/2020	06/11/2020
A30	29/09/2020	12/10/2020	16/11/2020	26/11/2020	30/11/2020	04/12/2020	04/12/2020
A31	17/11/2020	30/11/2020	04/01/2021	14/01/2021	18/01/2021	22/01/2021	22/01/2021
A32	10/12/2020	28/12/2020	01/02/2021	11/02/2021	15/02/2021	19/02/2021	19/02/2021
A33	12/01/2021	25/01/2021	01/03/2021	11/03/2021	15/03/2021	19/03/2021	19/03/2021
A34	09/02/2021	22/02/2021	29/03/2021	08/04/2021	12/04/2021	16/04/2021	16/04/2021
A35	05/03/2021	20/03/2021	26/04/2021	04/05/2021	07/05/2021	12/05/2021	12/05/2021
A36	13/04/2021	26/04/2021	31/05/2021	10/06/2021	14/06/2021	18/06/2021	18/06/2021
A37	11/05/2021	24/05/2021	28/06/2021	08/07/2021	12/07/2021	16/07/2021	16/07/2021
A38	08/06/2021	21/06/2021	26/07/2021	05/08/2021	09/08/2021	13/08/2021	13/08/2021
A39	06/07/2021	19/07/2021	23/08/2021	02/09/2021	06/09/2021	10/09/2021	10/09/2021
A40	03/08/2021	16/08/2021	20/09/2021	30/09/2021	04/10/2021	08/10/2021	08/10/2021
A41	31/08/2021	13/09/2021	18/10/2021	26/10/2021	29/10/2021	05/11/2021	05/11/2021
A42	05/10/2021	18/10/2021	22/11/2021	02/12/2021	06/12/2021	10/12/2021	10/12/2021

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

(-) 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	20/06/2018	21/06/2018	05/07/2018	12/07/2018	16/07/2018	20/07/2018	26/07/2018
B2	18/07/2018	19/07/2018	02/08/2018	09/08/2018	13/08/2018	17/08/2018	23/08/2018
B3	15/08/2018	16/08/2018	30/08/2018	06/09/2018	10/09/2018	14/09/2018	20/09/2018
B4	12/09/2018	13/09/2018	27/09/2018	04/10/2018	08/10/2018	12/10/2018	18/10/2018
B5	10/10/2018	11/10/2018	25/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
B6	07/11/2018	08/11/2018	22/11/2018	29/11/2018	03/12/2018	07/12/2018	13/12/2018
B7	21/12/2018	27/12/2018	10/01/2019	17/01/2019	21/01/2019	25/01/2019	25/01/2019
B8	23/01/2019	24/01/2019	07/02/2019	14/02/2019	18/02/2019	22/02/2019	22/02/2019
B9	20/02/2019	21/02/2019	07/03/2019	14/03/2019	18/03/2019	22/03/2019	22/03/2019
B10	18/03/2019	19/03/2019	02/04/2019	09/04/2019	12/04/2019	17/04/2019	17/04/2019
B11	24/04/2019	25/04/2019	10/05/2019	16/05/2019	20/05/2019	24/05/2019	24/05/2019
B12	22/05/2019	23/05/2019	06/06/2019	13/06/2019	17/06/2019	21/06/2019	21/06/2019
B13	19/06/2019	20/06/2019	04/07/2019	11/07/2019	15/07/2019	19/07/2019	19/07/2019
B14	17/07/2019	18/07/2019	01/08/2019	08/08/2019	12/08/2019	16/08/2019	16/08/2019
B15	14/08/2019	15/08/2019	29/08/2019	05/09/2019	09/09/2019	13/09/2019	13/09/2019
B16	11/09/2019	12/09/2019	26/09/2019	03/10/2019	07/10/2019	11/10/2019	11/10/2019
B17	09/10/2019	10/10/2019	24/10/2019	31/10/2019	04/11/2019	08/11/2019	08/11/2019
B18	06/11/2019	07/11/2019	21/11/2019	28/11/2019	02/12/2019	06/12/2019	06/12/2019
B19	23/12/2019	26/12/2019	09/01/2020	16/01/2020	20/01/2020	24/01/2020	24/01/2020
B20	22/01/2020	23/01/2020	06/02/2020	13/02/2020	17/02/2020	21/02/2020	21/02/2020
B21	19/02/2020	20/02/2020	05/03/2020	12/03/2020	16/03/2020	20/03/2020	20/03/2020
B22	25/03/2020	26/03/2020	08/04/2020	16/04/2020	20/04/2020	24/04/2020	24/04/2020
B23	20/04/2020	21/04/2020	05/05/2020	12/05/2020	15/05/2020	20/05/2020	20/05/2020
B24	20/05/2020	21/05/2020	04/06/2020	11/06/2020	15/06/2020	19/06/2020	19/06/2020
B25	17/06/2020	18/06/2020	02/07/2020	09/07/2020	13/07/2020	17/07/2020	17/07/2020
B26	15/07/2020	16/07/2020	30/07/2020	06/08/2020	10/08/2020	14/08/2020	14/08/2020
B27	12/08/2020	13/08/2020	27/08/2020	03/09/2020	07/09/2020	11/09/2020	11/09/2020
B28	09/09/2020	10/09/2020	24/09/2020	01/10/2020	05/10/2020	09/10/2020	09/10/2020
B29	07/10/2020	08/10/2020	22/10/2020	29/10/2020	03/11/2020	06/11/2020	06/11/2020
B30	04/11/2020	05/11/2020	19/11/2020	26/11/2020	30/11/2020	04/12/2020	04/12/2020
B31	23/12/2020	24/12/2020	07/01/2021	14/01/2021	18/01/2021	22/01/2021	22/01/2021
B32	20/01/2021	21/01/2021	04/02/2021	11/02/2021	15/02/2021	19/02/2021	19/02/2021
B33	17/02/2021	18/02/2021	04/03/2021	11/03/2021	15/03/2021	19/03/2021	19/03/2021
B34	17/03/2021	18/03/2021	31/03/2021	08/04/2021	12/04/2021	16/04/2021	16/04/2021
B35	12/04/2021	13/04/2021	27/04/2021	04/05/2021	07/05/2021	12/05/2021	12/05/2021
B36	19/05/2021	20/05/2021	03/06/2021	10/06/2021	14/06/2021	18/06/2021	18/06/2021
B37	16/06/2021	17/06/2021	01/07/2021	08/07/2021	12/07/2021	16/07/2021	16/07/2021
B38	14/07/2021	15/07/2021	29/07/2021	05/08/2021	09/08/2021	13/08/2021	13/08/2021
B39	11/08/2021	12/08/2021	26/08/2021	02/09/2021	06/09/2021	10/09/2021	10/09/2021
B40	08/09/2021	09/09/2021	23/09/2021	30/09/2021	04/10/2021	08/10/2021	08/10/2021
B41	06/10/2021	07/10/2021	21/10/2021	27/10/2021	29/10/2021	05/11/2021	05/11/2021
B42	10/11/2021	11/11/2021	25/11/2021	02/12/2021	06/12/2021	10/12/2021	10/12/2021

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(-) 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.

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	28/06/2018	29/06/2018	10/07/2018	13/07/2018	16/07/2018	20/07/2018	26/07/2018
C2	26/07/2018	27/07/2018	07/08/2018	10/08/2018	13/08/2018	17/08/2018	23/08/2018
C3	23/08/2018	24/08/2018	04/09/2018	07/09/2018	10/09/2018	14/09/2018	20/09/2018
C4	20/09/2018	21/09/2018	02/10/2018	05/10/2018	08/10/2018	12/10/2018	18/10/2018
C5	18/10/2018	19/10/2018	30/10/2018	31/10/2018	05/11/2018	09/11/2018	15/11/2018
C6	15/11/2018	16/11/2018	27/11/2018	30/11/2018	03/12/2018	07/12/2018	13/12/2018
C7	21/12/2018	02/01/2019	15/01/2019	18/01/2019	21/01/2019	25/01/2019	25/01/2019
C8	31/01/2019	01/02/2019	12/02/2019	15/02/2019	18/02/2019	22/02/2019	22/02/2019
C9	28/02/2019	01/03/2019	12/03/2019	15/03/2019	18/03/2019	22/03/2019	22/03/2019
C10	26/03/2019	27/03/2019	05/04/2019	09/04/2019	12/04/2019	17/04/2019	17/04/2019
C11	26/04/2019	29/04/2019	14/05/2019	17/05/2019	20/05/2019	24/05/2019	24/05/2019
C12	29/05/2019	31/05/2019	11/06/2019	14/06/2019	17/06/2019	21/06/2019	21/06/2019
C13	27/06/2019	28/06/2019	09/07/2019	12/07/2019	15/07/2019	19/07/2019	19/07/2019
C14	25/07/2019	26/07/2019	06/08/2019	09/08/2019	12/08/2019	16/08/2019	16/08/2019
C15	22/08/2019	23/08/2019	03/09/2019	06/09/2019	09/09/2019	13/09/2019	13/09/2019
C16	19/09/2019	20/09/2019	01/10/2019	04/10/2019	07/10/2019	11/10/2019	11/10/2019
C17	17/10/2019	18/10/2019	29/10/2019	31/10/2019	04/11/2019	08/11/2019	08/11/2019
C18	14/11/2019	15/11/2019	26/11/2019	29/11/2019	02/12/2019	06/12/2019	06/12/2019
C19	23/12/2019	27/12/2019	14/01/2020	17/01/2020	20/01/2020	24/01/2020	24/01/2020
C20	30/01/2020	31/01/2020	11/02/2020	14/02/2020	17/02/2020	21/02/2020	21/02/2020
C21	27/02/2020	28/02/2020	10/03/2020	13/03/2020	16/03/2020	20/03/2020	20/03/2020
C22	27/03/2020	30/03/2020	14/04/2020	17/04/2020	20/04/2020	24/04/2020	24/04/2020
C23	28/04/2020	29/04/2020	08/05/2020	12/05/2020	15/05/2020	20/05/2020	20/05/2020
C24	28/05/2020	29/05/2020	09/06/2020	12/06/2020	15/06/2020	19/06/2020	19/06/2020
C25	25/06/2020	26/06/2020	07/07/2020	10/07/2020	13/07/2020	17/07/2020	17/07/2020
C26	23/07/2020	24/07/2020	04/08/2020	07/08/2020	10/08/2020	14/08/2020	14/08/2020
C27	20/08/2020	21/08/2020	01/09/2020	04/09/2020	07/09/2020	11/09/2020	11/09/2020
C28	17/09/2020	18/09/2020	29/09/2020	02/10/2020	05/10/2020	09/10/2020	09/10/2020
C29	15/10/2020	16/10/2020	26/10/2020	29/10/2020	03/11/2020	06/11/2020	06/11/2020
C30	12/11/2020	13/11/2020	24/11/2020	27/11/2020	30/11/2020	04/12/2020	04/12/2020
C31	23/12/2020	25/12/2020	12/01/2021	15/01/2021	18/01/2021	22/01/2021	22/01/2021
C32	28/01/2021	29/01/2021	09/02/2021	12/02/2021	15/02/2021	19/02/2021	19/02/2021
C33	25/02/2021	26/02/2021	09/03/2021	12/03/2021	15/03/2021	19/03/2021	19/03/2021
C34	25/03/2021	26/03/2021	06/04/2021	09/04/2021	12/04/2021	16/04/2021	16/04/2021
C35	20/04/2021	21/04/2021	30/04/2021	04/05/2021	07/05/2021	12/05/2021	12/05/2021
C36	21/05/2021	25/05/2021	08/06/2021	11/06/2021	14/06/2021	18/06/2021	18/06/2021
C37	24/06/2021	25/06/2021	06/07/2021	09/07/2021	12/07/2021	16/07/2021	16/07/2021
C38	22/07/2021	23/07/2021	03/08/2021	06/08/2021	09/08/2021	13/08/2021	13/08/2021
C39	19/08/2021	20/08/2021	31/08/2021	03/09/2021	06/09/2021	10/09/2021	10/09/2021
C40	16/09/2021	17/09/2021	28/09/2021	01/10/2021	04/10/2021	08/10/2021	08/10/2021
C41	14/10/2021	15/10/2021	21/10/2021	27/10/2021	03/11/2021	05/11/2021	05/11/2021
C42	12/11/2021	15/11/2021	30/11/2021	03/12/2021	06/12/2021	10/12/2021	10/12/2021

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(-) 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.