



The timetables in this document may be subject to revision

Paediatric art. 46 submission (Post-Authorisation Measure)

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

	Deadline for Submission (*)	Start date	CHMP Rapporteur AR	Comments from CHMP (~)	Updated CHMP Rapporteur AR (#)	CHMP conclusion or Request for Supplementary Information
A43	14/05/2024	27/05/2024	01/07/2024	15/07/2024	18/07/2024	25/07/2024
A44	11/06/2024	24/06/2024	29/07/2024	12/08/2024	16/08/2024	22/08/2024
A45	09/07/2024	22/07/2024	26/08/2024	09/09/2024	12/09/2024	19/09/2024
A46	06/08/2024	19/08/2024	23/09/2024	07/10/2024	10/10/2024	17/10/2024
A47	03/09/2024	16/09/2024	21/10/2024	04/11/2024	07/11/2024	14/11/2024
A48	01/10/2024	14/10/2024	18/11/2024	02/12/2024	05/12/2024	12/12/2024

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 members are not made available to Marketing authorisation Holders (MAHs).

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

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

	Deadline for Submission (*)	Start date	CHMP Rapporteur AR	Comments from CHMP (~)	Updated CHMP Rapporteur AR (#)	CHMP conclusion
B1	23/12/2020	30/12/2020	13/01/2021	18/01/2021	21/01/2021	28/01/2021
B2	26/01/2021	27/01/2021	10/02/2021	15/02/2021	18/02/2021	25/02/2021
B3	23/02/2021	24/02/2021	10/03/2021	15/03/2021	18/03/2021	25/03/2021
B4	23/03/2021	24/03/2021	07/04/2021	12/04/2021	15/04/2021	22/04/2021
B5	20/04/2021	21/04/2021	05/05/2021	10/05/2021	12/05/2021	20/05/2021
B6	25/05/2021	26/05/2021	09/06/2021	14/06/2021	17/06/2021	24/06/2021
B7	22/06/2021	23/06/2021	07/07/2021	12/07/2021	15/07/2021	22/07/2021
B8	20/07/2021	21/07/2021	04/08/2021	09/08/2021	12/08/2021	19/08/2021
B9	17/08/2021	18/08/2021	01/09/2021	06/09/2021	09/09/2021	16/09/2021
B10	14/09/2021	15/09/2021	29/09/2021	04/10/2021	07/10/2021	14/10/2021
B11	12/10/2021	13/10/2021	26/10/2021	29/10/2021	04/11/2021	11/11/2021
B12	16/11/2021	17/11/2021	01/12/2021	06/12/2021	09/12/2021	16/12/2021
B13	22/12/2021	29/12/2021	12/01/2022	17/01/2022	20/01/2022	27/01/2022
B14	25/01/2022	26/01/2022	09/02/2022	14/02/2022	17/02/2022	24/02/2022
B15	22/02/2022	23/02/2022	09/03/2022	14/03/2022	17/03/2022	24/03/2022
B16	23/03/2022	24/03/2022	06/04/2022	11/04/2022	13/04/2022	22/04/2022
B17	19/04/2022	20/04/2022	04/05/2022	10/05/2022	12/05/2022	19/05/2022
B18	24/05/2022	25/05/2022	08/06/2022	13/06/2022	16/06/2022	23/06/2022
B19	21/06/2022	22/06/2022	06/07/2022	11/07/2022	14/07/2022	21/07/2022
B20	20/07/2022	21/07/2022	03/08/2022	08/08/2022	11/08/2022	19/08/2022
B21	16/08/2022	17/08/2022	31/08/2022	05/09/2022	08/09/2022	15/09/2022
B22	13/09/2022	14/09/2022	28/09/2022	03/10/2022	06/10/2022	13/10/2022
B23	11/10/2022	12/10/2022	26/10/2022	28/10/2022	03/11/2022	10/11/2022
B24	15/11/2022	16/11/2022	30/11/2022	05/12/2022	08/12/2022	15/12/2022
B25	22/12/2022	28/12/2022	11/01/2023	16/01/2023	19/01/2023	26/01/2023
B26	24/01/2023	25/01/2023	08/02/2023	13/02/2023	16/02/2023	23/02/2023
B27	28/02/2023	01/03/2023	15/03/2023	20/03/2023	23/03/2023	30/03/2023
B28	27/03/2023	28/03/2023	12/04/2023	17/04/2023	20/04/2023	26/04/2023
B29	25/04/2023	26/04/2023	10/05/2023	15/05/2023	17/05/2023	25/05/2023
B30	23/05/2023	24/05/2023	07/06/2023	12/06/2023	15/06/2023	22/06/2023
B31	20/06/2023	21/06/2023	05/07/2023	10/07/2023	13/07/2023	20/07/2023
B32	18/07/2023	19/07/2023	02/08/2023	07/08/2023	10/08/2023	17/08/2023
B33	14/08/2023	16/08/2023	30/08/2023	04/09/2023	07/09/2023	14/09/2023
B34	12/09/2023	13/09/2023	27/09/2023	02/10/2023	05/10/2023	12/10/2023
B35	10/10/2023	11/10/2023	25/10/2023	30/10/2023	06/11/2023	09/11/2023
B36	14/11/2023	15/11/2023	29/11/2023	04/12/2023	07/12/2023	14/12/2023
B37	21/12/2023	27/12/2023	10/01/2024	15/01/2024	18/01/2024	25/01/2024
B38	23/01/2024	24/01/2024	07/02/2024	12/02/2024	15/02/2024	22/02/2024
B39	20/02/2024	21/02/2024	06/03/2024	11/03/2024	14/03/2024	21/03/2024

	Deadline for Submission (*)	Start date	CHMP Rapporteur AR	Comments from CHMP (~)	Updated CHMP Rapporteur AR (#)	CHMP conclusion
B40	26/03/2024	27/03/2024	10/04/2024	15/04/2024	18/04/2024	25/04/2024
B41	30/04/2024	01/05/2024	15/05/2024	21/05/2024	23/05/2024	30/05/2024
B42	28/05/2024	29/05/2024	12/06/2024	17/06/2024	20/06/2024	27/06/2024
B43	25/06/2024	26/06/2024	10/07/2024	15/07/2024	18/07/2024	25/07/2024
B44	23/07/2024	24/07/2024	07/08/2024	12/08/2024	16/08/2024	22/08/2024
B45	20/08/2024	21/08/2024	04/09/2024	09/09/2024	12/09/2024	19/09/2024
B46	17/09/2024	18/09/2024	02/10/2024	07/10/2024	10/10/2024	17/10/2024
B47	15/10/2024	16/10/2024	30/10/2024	04/11/2024	07/11/2024	14/11/2024
B48	12/11/2024	13/11/2024	27/11/2024	02/12/2024	05/12/2024	12/12/2024

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(~) Comments from CHMP members are not made available to Marketing authorisation Holders (MAHs).

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

30-day immediate responses to RSI assessment timetable

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

	Deadline for Submission (*)	Start date	CHMP Rapporteur AR	Comments from CHMP (~)	Updated CHMP Rapporteur AR (#)	CHMP conclusion
C42	04/06/2024	05/06/2024	12/06/2024	17/06/2024	20/06/2024	27/06/2024
C43	02/07/2024	03/07/2024	10/07/2024	15/07/2024	18/07/2024	25/07/2024
C44	30/07/2024	31/07/2024	07/08/2024	12/08/2024	16/08/2024	22/08/2024
C45	27/08/2024	28/08/2024	04/09/2024	09/09/2024	12/09/2024	19/09/2024
C46	24/09/2024	25/09/2024	02/10/2024	07/10/2024	10/10/2024	17/10/2024
C47	22/10/2024	23/10/2024	30/10/2024	04/11/2024	07/11/2024	14/11/2024
C48	19/11/2024	20/11/2024	27/11/2024	02/12/2024	05/12/2024	12/12/2024

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