

12 December 2018
EMA/823131/2015 Rev.2
Human Medicines Evaluation

[The timetables in this document may be subject to revision](#)

Annual renewal application of conditional marketing authorisation*

[Assessment of initial submission \(60-day timetable\)](#)

[Assessment of responses to Request for Supplementary Information \(30-day timetable after immediate responses\)](#)

(*) This type of application applies to conditional marketing authorisations granted in accordance with Article 14(7) of Regulation (EC) No 726/2004 and Regulation (EC) No 507/2006

Assessment of initial submission

60-day timetable

	Deadline for Submission (*)	Start date (^)	CHMP and PRAC Rapporteur Joint AR	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteur Joint AR (***)	PRAC outcome	Request for Supplementary Information (RSI) or Opinion
A1	05/01/2018	22/01/2018	20/02/2018	26/02/2018	01/03/2018	08/03/2018	22/03/2018
A2	09/02/2018	26/02/2018	27/03/2018	03/04/2018	05/04/2018	12/04/2018	26/04/2018
A3	16/03/2018	02/04/2018	30/04/2018	04/05/2018	08/05/2018	17/05/2018	31/05/2018
A4	13/04/2018	30/04/2018	29/05/2018	04/06/2018	07/06/2018	14/06/2018	28/06/2018
A5	08/05/2018	28/05/2018	26/06/2018	02/07/2018	05/07/2018	12/07/2018	26/07/2018
A6							
A7	06/07/2018	23/07/2018	21/08/2018	28/08/2018	30/08/2018	06/09/2018	20/09/2018
A8	03/08/2018	20/08/2018	18/09/2018	24/09/2018	27/09/2018	04/10/2018	18/10/2018
A9	31/08/2018	17/09/2018	16/10/2018	22/10/2018	25/10/2018	31/10/2018	15/11/2018
A10	28/09/2018	15/10/2018	13/11/2018	19/11/2018	22/11/2018	29/11/2018	13/12/2018
A11	16/11/2018	03/12/2018	03/01/2019	07/01/2019	10/01/2019	17/01/2019	31/01/2019
A12	30/11/2018	31/12/2018	29/01/2019	04/02/2019	07/02/2019	14/02/2019	28/02/2019
A13	11/01/2019	28/01/2019	26/02/2019	04/03/2019	07/03/2019	14/03/2019	28/03/2019
A14	08/02/2019	26/02/2019	26/03/2019	01/04/2019	04/04/2019	11/04/2019	26/04/2019
A15	14/03/2019	31/03/2019	30/04/2019	06/05/2019	08/05/2019	16/05/2019	29/05/2019
A16	12/04/2019	29/04/2019	28/05/2019	03/06/2019	06/06/2019	14/06/2019	27/06/2019
A17	10/05/2019	27/05/2019	25/06/2019	01/07/2019	04/07/2019	11/07/2019	25/07/2019
A18							
A19	05/07/2019	22/07/2019	20/08/2019	27/08/2019	29/08/2019	05/09/2019	19/09/2019
A20	02/08/2019	19/08/2019	17/09/2019	23/09/2019	26/09/2019	03/10/2019	17/10/2019
A21	30/08/2019	16/09/2019	15/10/2019	21/10/2019	24/10/2019	31/10/2019	14/11/2019
A22	27/09/2019	14/10/2019	12/11/2019	18/11/2019	21/11/2019	28/11/2019	12/12/2019
A23	15/11/2019	02/12/2019	03/01/2020	07/01/2020	09/01/2020	16/01/2020	30/01/2020
A24	29/11/2019	30/12/2019	28/01/2020	03/02/2020	06/02/2020	13/02/2020	27/02/2020
A25	10/01/2020	27/01/2020	25/02/2020	02/03/2020	05/03/2020	12/03/2020	26/03/2020
A26	14/02/2020	02/03/2020	31/03/2020	06/04/2020	08/04/2020	17/04/2020	30/04/2020
A27	13/03/2020	30/03/2020	28/04/2020	04/05/2020	07/05/2020	14/05/2020	28/05/2020
A28	08/04/2020	27/04/2020	26/05/2020	02/06/2020	04/06/2020	11/06/2020	25/06/2020
A29	08/05/2020	25/05/2020	23/06/2020	29/06/2020	02/07/2020	09/07/2020	23/07/2020
A30							
A31	03/07/2020	20/07/2020	18/08/2020	24/08/2020	27/08/2020	04/09/2020	17/09/2020
A32	31/07/2020	17/08/2020	15/09/2020	21/09/2020	24/09/2020	01/10/2020	15/10/2020
A33	28/08/2020	14/09/2020	13/10/2020	19/10/2020	22/10/2020	29/10/2020	12/11/2020
A34	25/09/2020	12/10/2020	10/11/2020	16/11/2020	19/11/2020	26/11/2020	10/12/2020
A35	13/11/2020	30/11/2020	22/12/2020	04/01/2021	07/01/2021	14/01/2021	28/01/2021
A36	27/11/2020	28/12/2020	26/01/2021	01/02/2021	04/02/2021	11/02/2021	25/02/2021
A37	08/01/2021	25/01/2021	23/02/2021	01/03/2021	04/03/2021	11/03/2021	25/03/2021
A38	05/02/2021	22/02/2021	23/03/2021	29/03/2021	31/03/2021	09/04/2021	22/04/2021

	Deadline for Submission (*)	Start date (^)	CHMP and PRAC Rapporteur Joint AR	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteur Joint AR (***)	PRAC outcome	Request for Supplementary Information (RSI) or Opinion
A39	05/03/2021	22/03/2021	20/04/2021	26/04/2021	29/04/2021	06/05/2021	20/05/2021
A40	09/04/2021	26/04/2021	25/05/2021	31/05/2021	03/06/2021	10/06/2021	24/06/2021
A41	07/05/2021	24/05/2021	22/06/2021	28/06/2021	01/07/2021	08/07/2021	22/07/2021
A42							
A43	02/07/2021	19/07/2021	17/08/2021	23/08/2021	26/08/2021	03/09/2021	16/09/2021
A44	30/07/2021	16/08/2021	14/09/2021	20/09/2021	23/09/2021	30/09/2021	14/10/2021
A45	27/08/2021	13/09/2021	12/10/2021	18/10/2021	21/10/2021	28/10/2021	11/11/2021
A46	01/10/2021	18/10/2021	16/11/2021	22/11/2021	25/11/2021	02/12/2021	16/12/2021

(*) Renewal applications must be submitted at least six months before the actual expiry date of the marketing authorisation, i.e. the 1-year anniversary of the Commission Decision granting or renewing the marketing authorisation and irrespective of whether the marketing authorisation may be suspended. The start of the evaluation process will be the next possible date in the table after submission and validation of the dossier. The MAHs should agree in advance the submission date of the renewal application with the Agency.

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 needs to be re-despatched.

(^) The validation period between submission date and start date is usually sixteen calendar days.

(**) Comments from PRAC and CHMP members are not made available to Marketing Authorisation Holders.

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

Assessment of responses to Request for Supplementary Information

30-day timetable after immediate responses

	Deadline for Submission (*)	Re-start date	CHMP and PRAC Rapporteur Joint AR	PRAC outcome	Comments from CHMP (**)	Updated CHMP and PRAC Rapporteur Joint AR (***)	Opinion
B1	30/01/2018	31/01/2018	07/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
B2	27/02/2018	28/02/2018	07/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
B3	27/03/2018	04/04/2018	11/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
B4	30/04/2018	09/05/2018	16/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
B5	05/06/2018	06/06/2018	13/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
B6	03/07/2018	04/07/2018	11/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
B7							
B8	21/08/2018	29/08/2018	05/09/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
B9	25/09/2018	26/09/2018	03/10/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
B10	23/10/2018	24/10/2018	31/10/2018	01/11/2018	05/11/2018	08/11/2018	15/11/2018
B11	20/11/2018	21/11/2018	28/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
B12	21/12/2018	02/01/2019	16/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019
B13	05/02/2019	06/02/2019	13/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019
B14	05/03/2019	06/03/2019	13/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019
B15	03/04/2019	04/04/2019	10/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
B16	02/05/2019	03/05/2019	15/05/2019	16/05/2019	20/05/2019	23/05/2019	29/05/2019
B17	04/06/2019	05/06/2019	12/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
B18	02/07/2019	03/07/2019	10/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
B19							
B20	20/08/2019	21/08/2019	04/09/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
B21	24/09/2019	25/09/2019	02/10/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
B22	22/10/2019	23/10/2019	30/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
B23	19/11/2019	20/11/2019	27/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
B24	23/12/2019	01/01/2020	15/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
B25	04/02/2020	05/02/2020	12/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
B26	03/03/2020	04/03/2020	11/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
B27	02/04/2020	03/04/2020	15/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
B28	05/05/2020	06/05/2020	13/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
B29	02/06/2020	03/06/2020	10/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
B30	30/06/2020	01/07/2020	08/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
B31							
B32	18/08/2020	19/08/2020	02/09/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
B33	22/09/2020	23/09/2020	30/09/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
B34	20/10/2020	21/10/2020	28/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
B35	17/11/2020	18/11/2020	25/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
B36	23/12/2020	30/12/2020	13/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
B37	02/02/2021	03/02/2021	10/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
B38	02/03/2021	03/03/2021	10/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
B39	30/03/2021	31/03/2021	07/04/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
B40	27/04/2021	28/04/2021	05/05/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021

B41	27/05/2021	28/05/2021	09/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
B42	29/06/2021	30/06/2021	07/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
B43							
B44	17/08/2021	18/08/2021	01/09/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
B45	21/09/2021	22/09/2021	29/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
B46	19/10/2021	20/10/2021	27/10/2021	28/10/2021	03/11/2021	05/11/2021	11/11/2021
B47	18/11/2021	19/11/2021	01/12/2021	02/12/2021	06/12/2021	09/12/2021	16/12/2021

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