

5 March 2018  
EMA/461220/2015 Rev.2  
Human Medicines Evaluation

The timetables in this document may be subject to revision

## Marketing authorisation renewal application

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

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

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

# Assessment of initial submission

## 90-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	10/01/2018	27/01/2018	27/03/2018	03/04/2018	05/04/2018	12/04/2018	26/04/2018
A2	14/02/2018	03/03/2018	30/04/2018	06/05/2018	08/05/2018	17/05/2018	31/05/2018
A3	14/03/2018	31/03/2018	29/05/2018	04/06/2018	07/06/2018	14/06/2018	28/06/2018
A4	11/04/2018	28/04/2018	26/06/2018	02/07/2018	05/07/2018	12/07/2018	26/07/2018
A5							
A6	06/06/2018	23/06/2018	21/08/2018	28/08/2018	30/08/2018	06/09/2018	20/09/2018
A7	04/07/2018	21/07/2018	18/09/2018	24/09/2018	27/09/2018	04/10/2018	18/10/2018
A8	01/08/2018	18/08/2018	16/10/2018	22/10/2018	25/10/2018	31/10/2018	15/11/2018
A9	29/08/2018	15/09/2018	13/11/2018	19/11/2018	22/11/2018	29/11/2018	13/12/2018
A10	17/10/2018	03/11/2018	20/12/2018	07/01/2019	10/01/2019	17/01/2019	31/01/2019
A11	14/11/2018	01/12/2018	29/01/2019	04/02/2019	07/02/2019	14/02/2019	28/02/2019
A12	26/11/2018	29/12/2018	26/02/2019	04/03/2019	07/03/2019	14/03/2019	28/03/2019
A13	10/01/2019	27/01/2019	26/03/2019	01/04/2019	04/04/2019	11/04/2019	26/04/2019
A14	12/02/2019	01/03/2019	30/04/2019	06/05/2019	08/05/2019	16/05/2019	29/05/2019
A15	13/03/2019	30/03/2019	28/05/2019	03/06/2019	06/06/2019	14/06/2019	27/06/2019
A16	10/04/2019	27/04/2019	25/06/2019	01/07/2019	04/07/2019	11/07/2019	25/07/2019
A17							
A18	05/06/2019	22/06/2019	20/08/2019	27/08/2019	29/08/2019	05/09/2019	19/09/2019
A19	03/07/2019	20/07/2019	17/09/2019	23/09/2019	26/09/2019	03/10/2019	17/10/2019
A20	31/07/2019	17/08/2019	15/10/2019	21/10/2019	24/10/2019	31/10/2019	14/11/2019
A21	28/08/2019	14/09/2019	12/11/2019	18/11/2019	21/11/2019	28/11/2019	12/12/2019
A22	16/10/2019	02/11/2019	20/12/2019	06/01/2020	09/01/2020	16/01/2020	30/01/2020
A23	13/11/2019	30/11/2019	28/01/2020	03/02/2020	06/02/2020	13/02/2020	27/02/2020
A24	25/11/2019	28/12/2019	25/02/2020	02/03/2020	05/03/2020	12/03/2020	26/03/2020
A25	15/01/2020	01/02/2020	31/03/2020	06/04/2020	08/04/2020	17/04/2020	30/04/2020
A26	12/02/2020	29/02/2020	28/04/2020	04/05/2020	07/05/2020	14/05/2020	28/05/2020
A27	11/03/2020	28/03/2020	26/05/2020	02/06/2020	04/06/2020	11/06/2020	25/06/2020
A28	03/04/2020	25/04/2020	23/06/2020	29/06/2020	02/07/2020	09/07/2020	23/07/2020
A29							
A30	03/06/2020	20/06/2020	18/08/2020	24/08/2020	27/08/2020	04/09/2020	17/09/2020
A31	01/07/2020	18/07/2020	15/09/2020	21/09/2020	24/09/2020	01/10/2020	15/10/2020
A32	29/07/2020	15/08/2020	13/10/2020	19/10/2020	22/10/2020	29/10/2020	12/11/2020
A33	26/08/2020	12/09/2020	10/11/2020	16/11/2020	19/11/2020	26/11/2020	10/12/2020
A34	14/10/2020	31/10/2020	22/12/2020	04/01/2021	07/01/2021	14/01/2021	28/01/2021
A35	11/11/2020	28/11/2020	26/01/2021	01/02/2021	04/02/2021	11/02/2021	25/02/2021
A36	25/11/2020	26/12/2020	23/02/2021	01/03/2021	04/03/2021	11/03/2021	25/03/2021
A37	06/01/2021	23/01/2021	23/03/2021	29/03/2021	31/03/2021	09/04/2021	22/04/2021
A38	03/02/2021	20/02/2021	20/04/2021	26/04/2021	29/04/2021	06/05/2021	20/05/2021

	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	10/03/2021	27/03/2021	25/05/2021	31/05/2021	03/06/2021	10/06/2021	24/06/2021
A40	07/04/2021	24/04/2021	22/06/2021	28/06/2021	01/07/2021	08/07/2021	22/07/2021
A41							
A42	02/06/2021	19/06/2021	17/08/2021	23/08/2021	26/08/2021	03/09/2021	16/09/2021
A43	30/06/2021	17/07/2021	14/09/2021	20/09/2021	23/09/2021	30/09/2021	14/10/2021
A44	28/07/2021	14/08/2021	12/10/2021	18/10/2021	21/10/2021	28/10/2021	11/11/2021
A45	01/09/2021	18/09/2021	16/11/2021	22/11/2021	25/11/2021	02/12/2021	16/12/2021

(\*) Renewal applications must be submitted at least nine months before the actual expiry date of the marketing authorisation, i.e. the 5-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 it 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 clock-stop for responses

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

	Deadline for Submission (*)	Re-start date	CHMP and PRAC Rapporteur Joint AR	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteur Joint AR (***)	PRAC outcome	Opinion
B39	23/03/2021	24/03/2021	29/03/2021	30/03/2021	31/03/2021	09/04/2021	22/04/2021
B40	20/04/2021	21/04/2021	26/04/2021	28/04/2021	29/04/2021	06/05/2021	20/05/2021
B41	25/05/2021	26/05/2021	31/05/2021	02/06/2021	03/06/2021	10/06/2021	24/06/2021
B42	22/06/2021	23/06/2021	28/06/2021	30/06/2021	01/07/2021	08/07/2021	22/07/2021
B43							
B44	17/08/2021	18/08/2021	23/08/2021	25/08/2021	26/08/2021	03/09/2021	16/09/2021
B45	14/09/2021	15/09/2021	20/09/2021	22/09/2021	23/09/2021	30/09/2021	14/10/2021
B46	12/10/2021	13/10/2021	18/10/2021	20/10/2021	21/10/2021	28/10/2021	11/11/2021
B47	16/11/2021	17/11/2021	22/11/2021	24/11/2021	25/11/2021	02/12/2021	16/12/2021

(\*) 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 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<sup>1</sup>

	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
C1	30/01/2018	31/01/2018	07/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
C2	27/02/2018	28/02/2018	07/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
C3	27/03/2018	04/04/2018	11/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
C4	30/04/2018	09/05/2018	16/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
C5	05/06/2018	06/06/2018	13/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
C6	03/07/2018	04/07/2018	11/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
C7							
C8	21/08/2018	29/08/2018	05/09/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
C9	25/09/2018	26/09/2018	03/10/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
C10	23/10/2018	24/10/2018	31/10/2018	01/11/2018	05/11/2018	08/11/2018	15/11/2018
C11	20/11/2018	21/11/2018	28/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
C12	21/12/2018	02/01/2019	16/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019
C13	05/02/2019	06/02/2019	13/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019
C14	05/03/2019	06/03/2019	13/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019
C15	03/04/2019	04/04/2019	10/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
C16	02/05/2019	03/05/2019	15/05/2019	16/05/2019	20/05/2019	23/05/2019	29/05/2019
C17	04/06/2019	05/06/2019	12/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
C18	02/07/2019	03/07/2019	10/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
C19							
C20	20/08/2019	21/08/2019	04/09/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
C21	24/09/2019	25/09/2019	02/10/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
C22	22/10/2019	23/10/2019	30/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
C23	19/11/2019	20/11/2019	27/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
C24	23/12/2019	01/01/2020	15/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
C25	04/02/2020	05/02/2020	12/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
C26	03/03/2020	04/03/2020	11/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
C27	02/04/2020	03/04/2020	15/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
C28	05/05/2020	06/05/2020	13/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
C29	02/06/2020	03/06/2020	10/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
C30	30/06/2020	01/07/2020	08/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
C31							
C32	18/08/2020	19/08/2020	02/09/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
C33	22/09/2020	23/09/2020	30/09/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
C34	20/10/2020	21/10/2020	28/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
C35	17/11/2020	18/11/2020	25/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
C36	23/12/2020	30/12/2020	13/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
C37	02/02/2021	03/02/2021	10/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
C38	02/03/2021	03/03/2021	10/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021

	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
C39	30/03/2021	31/03/2021	07/04/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
C40	27/04/2021	28/04/2021	05/05/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
C41	27/05/2021	28/05/2021	09/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
C42	29/06/2021	30/06/2021	07/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
C43							
C44	17/08/2021	18/08/2021	01/09/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
C45	21/09/2021	22/09/2021	29/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
C46	19/10/2021	20/10/2021	27/10/2021	28/10/2021	03/11/2021	05/11/2021	11/11/2021
C47	18/11/2021	19/11/2021	01/12/2021	02/12/2021	06/12/2021	09/12/2021	16/12/2021

(<sup>1</sup>) This timetable is only applicable when minor issues remain.

(\*) 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 members are not made available to Marketing Authorisation Holders.

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