



17 November 2022  
EMA/823131/2015 Rev.4  
Human Medicines Division

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	10/01/2020	27/01/2020	25/02/2020	02/03/2020	05/03/2020	12/03/2020	26/03/2020
A2	14/02/2020	02/03/2020	31/03/2020	06/04/2020	08/04/2020	17/04/2020	30/04/2020
A3	13/03/2020	30/03/2020	28/04/2020	04/05/2020	07/05/2020	14/05/2020	28/05/2020
A4	08/04/2020	27/04/2020	26/05/2020	02/06/2020	04/06/2020	11/06/2020	25/06/2020
A5	08/05/2020	25/05/2020	23/06/2020	29/06/2020	02/07/2020	09/07/2020	23/07/2020
A6							
A7	03/07/2020	20/07/2020	18/08/2020	24/08/2020	27/08/2020	04/09/2020	17/09/2020
A8	31/07/2020	17/08/2020	15/09/2020	21/09/2020	24/09/2020	01/10/2020	15/10/2020
A9	28/08/2020	14/09/2020	13/10/2020	19/10/2020	22/10/2020	29/10/2020	12/11/2020
A10	25/09/2020	12/10/2020	10/11/2020	16/11/2020	19/11/2020	26/11/2020	10/12/2020
A11	13/11/2020	30/11/2020	22/12/2020	04/01/2021	07/01/2021	14/01/2021	28/01/2021
A12	27/11/2020	28/12/2020	26/01/2021	01/02/2021	04/02/2021	11/02/2021	25/02/2021
A13	08/01/2021	25/01/2021	23/02/2021	01/03/2021	04/03/2021	11/03/2021	25/03/2021
A14	05/02/2021	22/02/2021	23/03/2021	29/03/2021	31/03/2021	09/04/2021	22/04/2021
A15	05/03/2021	22/03/2021	20/04/2021	26/04/2021	29/04/2021	06/05/2021	20/05/2021
A16	09/04/2021	26/04/2021	25/05/2021	31/05/2021	03/06/2021	10/06/2021	24/06/2021
A17	07/05/2021	24/05/2021	22/06/2021	28/06/2021	01/07/2021	08/07/2021	22/07/2021
A18							
A19	02/07/2021	19/07/2021	17/08/2021	23/08/2021	26/08/2021	03/09/2021	16/09/2021
A20	30/07/2021	16/08/2021	14/09/2021	20/09/2021	23/09/2021	30/09/2021	14/10/2021
A21	27/08/2021	13/09/2021	12/10/2021	18/10/2021	21/10/2021	28/10/2021	11/11/2021
A22	01/10/2021	18/10/2021	16/11/2021	22/11/2021	25/11/2021	02/12/2021	16/12/2021

	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
A23	12/11/2021	29/11/2021	22/12/2021	03/01/2022	06/01/2022	13/01/2022	27/01/2022
A24	26/11/2021	27/12/2021	25/01/2022	31/01/2022	03/02/2022	10/02/2022	24/02/2022
A25	07/01/2022	24/01/2022	22/02/2022	28/02/2022	03/03/2022	10/03/2022	24/03/2022
A26	04/02/2022	22/02/2022	22/03/2022	28/03/2022	31/03/2022	07/04/2022	22/04/2022
A27	04/03/2022	21/03/2022	19/04/2022	25/04/2022	28/04/2022	05/05/2022	19/05/2022
A28	08/04/2022	25/04/2022	24/05/2022	30/05/2022	02/06/2022	10/06/2022	23/06/2022
A29	06/05/2022	23/05/2022	21/06/2022	27/06/2022	30/06/2022	07/07/2022	21/07/2022
A30							
A31	01/07/2022	18/07/2022	16/08/2022	22/08/2022	25/08/2022	01/09/2022	15/09/2022
A32	29/07/2022	15/08/2022	13/09/2022	19/09/2022	22/09/2022	29/09/2022	13/10/2022
A33	26/08/2022	12/09/2022	11/10/2022	17/10/2022	20/10/2022	27/10/2022	10/11/2022
A34	30/09/2022	17/10/2022	15/11/2022	21/11/2022	24/11/2022	01/12/2022	15/12/2022
A35	11/11/2022	28/11/2022	22/12/2022	03/01/2023	05/01/2023	12/01/2023	26/01/2023
A36	25/11/2022	26/12/2022	24/01/2023	30/01/2023	02/02/2023	09/02/2023	23/02/2023
A37	13/01/2023	30/01/2023	28/02/2023	06/03/2023	09/03/2023	16/03/2023	30/03/2023
A38	09/02/2023	26/02/2023	28/03/2023	03/04/2023	05/04/2023	14/04/2023	26/04/2023
A39	10/03/2023	27/03/2023	25/04/2023	02/05/2023	04/05/2023	12/05/2023	25/05/2023
A40	05/04/2023	24/04/2023	23/05/2023	30/05/2023	01/06/2023	08/06/2023	22/06/2023
A41	05/05/2023	22/05/2023	20/06/2023	26/06/2023	29/06/2023	06/07/2023	20/07/2023
A42							
A43	30/06/2023	17/07/2023	14/08/2023	21/08/2023	24/08/2023	31/08/2023	14/09/2023
A44	28/07/2023	14/08/2023	12/09/2023	18/09/2023	21/09/2023	28/09/2023	12/10/2023
A45	25/08/2023	11/09/2023	10/10/2023	16/10/2023	19/10/2023	26/10/2023	09/11/2023
A46	29/09/2023	16/10/2023	14/11/2023	20/11/2023	23/11/2023	30/11/2023	14/12/2023
A47	10/11/2023	27/11/2023	21/12/2023	03/01/2024	05/01/2024	11/01/2024	25/01/2024

	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
A48	24/11/2023	25/12/2023	23/01/2024	29/01/2024	01/02/2024	08/02/2024	22/02/2024
A49	05/01/2024	22/01/2024	20/02/2024	26/02/2024	29/02/2024	07/03/2024	21/03/2024
A50	09/02/2024	26/02/2024	26/03/2024	02/04/2024	04/04/2024	11/04/2024	25/04/2024
A51	15/03/2024	01/04/2024	30/04/2024	06/05/2024	08/05/2024	16/05/2024	30/05/2024
A52	12/04/2024	29/04/2024	28/05/2024	03/06/2024	06/06/2024	13/06/2024	27/06/2024
A53	08/05/2024	27/05/2024	25/06/2024	01/07/2024	04/07/2024	11/07/2024	25/07/2024
A54							
A55	05/07/2024	22/07/2024	20/08/2024	26/08/2024	29/08/2024	05/09/2024	19/09/2024
A56	02/08/2024	19/08/2024	17/09/2024	23/09/2024	26/09/2024	03/10/2024	17/10/2024
A57	30/08/2024	16/09/2024	15/10/2024	21/10/2024	24/10/2024	31/10/2024	14/11/2024
A58	27/09/2024	14/10/2024	12/11/2024	18/11/2024	21/11/2024	28/11/2024	12/12/2024

(\*) 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	04/02/2020	05/02/2020	12/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
B2	03/03/2020	04/03/2020	11/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
B3	02/04/2020	03/04/2020	15/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
B4	05/05/2020	06/05/2020	13/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
B5	02/06/2020	03/06/2020	10/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
B6	30/06/2020	01/07/2020	08/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
B7							
B8	18/08/2020	19/08/2020	02/09/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
B9	22/09/2020	23/09/2020	30/09/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
B10	20/10/2020	21/10/2020	28/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
B11	17/11/2020	18/11/2020	25/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
B12	23/12/2020	30/12/2020	13/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
B13	02/02/2021	03/02/2021	10/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
B14	02/03/2021	03/03/2021	10/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
B15	30/03/2021	31/03/2021	07/04/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
B16	27/04/2021	28/04/2021	05/05/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
B17	27/05/2021	28/05/2021	09/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
B18	29/06/2021	30/06/2021	07/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
B19							
B20	17/08/2021	18/08/2021	01/09/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
B21	21/09/2021	22/09/2021	29/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
B22	19/10/2021	20/10/2021	27/10/2021	28/10/2021	03/11/2021	05/11/2021	11/11/2021
B23	18/11/2021	19/11/2021	01/12/2021	02/12/2021	06/12/2021	09/12/2021	16/12/2021
B24	22/12/2021	29/12/2021	12/01/2022	13/01/2022	17/01/2022	20/01/2022	27/01/2022
B25	01/02/2022	02/02/2022	09/02/2022	10/02/2022	14/02/2022	17/02/2022	24/02/2022
B26	01/03/2022	02/03/2022	09/03/2022	10/03/2022	14/03/2022	17/03/2022	24/03/2022
B27	30/03/2022	31/03/2022	06/04/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
B28	26/04/2022	27/04/2022	04/05/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
B29	25/05/2022	27/05/2022	08/06/2022	10/06/2022	13/06/2022	16/06/2022	23/06/2022
B30	28/06/2022	29/06/2022	06/07/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
B31							
B32	16/08/2022	17/08/2022	31/08/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
B33	20/09/2022	21/09/2022	28/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
B34	18/10/2022	19/10/2022	26/10/2022	27/10/2022	28/10/2022	03/11/2022	10/11/2022
B35	16/11/2022	18/11/2022	30/11/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
B36	22/12/2022	28/12/2022	11/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
B37	31/01/2023	01/02/2023	08/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
B38	28/02/2023	01/03/2023	15/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
B39	03/04/2023	04/04/2023	11/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
B40	02/05/2023	03/05/2023	10/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023

	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
B41	30/05/2023	31/05/2023	07/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
B42	27/06/2023	28/06/2023	05/07/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
B43							
B44	14/08/2023	16/08/2023	30/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
B45	19/09/2023	20/09/2023	27/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
B46	17/10/2023	18/10/2023	25/10/2023	26/10/2023	30/10/2023	31/10/2023	09/11/2023
B47	16/11/2023	17/11/2023	29/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
B48	21/12/2023	27/12/2023	10/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
B49	30/01/2024	31/01/2024	07/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
B50	27/02/2024	28/02/2024	06/03/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024
B51	27/03/2024	29/03/2024	10/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024
B52	02/05/2024	03/05/2024	15/05/2024	16/05/2024	21/05/2024	23/05/2024	30/05/2024
B53	04/06/2024	05/06/2024	12/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024
B54	02/07/2024	03/07/2024	10/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024
B55							
B56	20/08/2024	21/08/2024	04/09/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
B57	24/09/2024	25/09/2024	02/10/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
B58	22/10/2024	23/10/2024	30/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
B59	19/11/2024	20/11/2024	27/11/2024	28/11/2024	02/12/2024	05/12/2024	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 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.