



19 April 2021
EMA/488671/2015 Rev.5
Human Medicines Division

The timetables in this document may be subject to revision

Informed consent and multiple application*

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

[Assessment of responses to List of Questions \(LOQ\)](#)

[Assessment of responses to List of Outstanding Issues \(30-day timetable after clock-stop for responses\)](#)

[Assessment of responses to List of Outstanding Issues \(30-day timetable after immediate responses\)](#)

(*) This timetable only applies to multiples of identical products with existing marketing authorisations. If the product of the multiple application is not identical to an existing product (authorised or under assessment), then an independent timetable for a full marketing authorisation application will apply to the multiple application. On the other hand, a multiple of an identical product with an ongoing marketing authorisation application will follow the same timetable as the ongoing application. However, there should be adequate time for validation of the multiple application. Therefore, the initial submission deadline of this timetable still applies in these cases (i.e. the application should be submitted following the deadline of the initial submission above and e.g. well ahead of any planned responses to the List of Questions for the parent product application).

Assessment of initial submission (60-day timetable)

	Deadline for Submission (*)	Start (^)	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (~)	Comments from PRAC (**) (~)	PRAC outcome (~) (#)	Updated PRAC Rapporteur AR (~) (***)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	List of Questions (LoQ) or Opinion
A1	07/01/2020	27/01/2020	02/03/2020	06/03/2020	12/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
A2	11/02/2020	02/03/2020	06/04/2020	08/04/2020	17/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
A3	10/03/2020	30/03/2020	04/05/2020	08/05/2020	14/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
A4	02/04/2020	27/04/2020	01/06/2020	05/06/2020	11/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
A5	30/04/2020	25/05/2020	29/06/2020	03/07/2020	09/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
A6									
A7	30/06/2020	20/07/2020	24/08/2020	28/08/2020	04/09/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
A8	28/07/2020	17/08/2020	21/09/2020	25/09/2020	01/10/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
A9	24/08/2020	14/09/2020	19/10/2020	23/10/2020	29/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
A10	22/09/2020	12/10/2020	16/11/2020	20/11/2020	26/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
A11	10/11/2020	30/11/2020	04/01/2021	08/01/2021	14/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
A12	01/12/2020	28/12/2020	01/02/2021	05/02/2021	11/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
A13	05/01/2021	25/01/2021	01/03/2021	05/03/2021	11/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
A14	02/02/2021	22/02/2021	29/03/2021	02/04/2021	09/04/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
A15	02/03/2021	22/03/2021	26/04/2021	30/04/2021	06/05/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
A16	06/04/2021	26/04/2021	31/05/2021	04/06/2021	10/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
A17	29/04/2021	24/05/2021	28/06/2021	02/07/2021	08/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
A18									
A19	29/06/2021	19/07/2021	23/08/2021	27/08/2021	03/09/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
A20	27/07/2021	16/08/2021	20/09/2021	24/09/2021	30/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
A21	23/08/2021	13/09/2021	18/10/2021	22/10/2021	28/10/2021	28/10/2021	29/10/2021	04/11/2021	11/11/2021
A22	28/09/2021	18/10/2021	22/11/2021	26/11/2021	02/12/2021	02/12/2021	06/12/2021	09/12/2021	16/12/2021
A23	09/11/2021	29/11/2021	03/01/2022	07/01/2022	13/01/2022	13/01/2022	17/01/2022	20/01/2022	27/01/2022
A24	30/11/2021	27/12/2021	31/01/2022	04/02/2022	10/02/2022	10/02/2022	14/02/2022	17/02/2022	24/02/2022
A25	04/01/2022	24/01/2022	28/02/2022	04/03/2022	10/03/2022	10/03/2022	14/03/2022	17/03/2022	24/03/2022

	Deadline for Submission (*)	Start (^)	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (~)	Comments from PRAC (**) (~)	PRAC outcome (~) (#)	Updated PRAC Rapporteur AR (~) (***)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	List of Questions (LoQ) or Opinion
A26	02/02/2022	22/02/2022	28/03/2022	01/04/2022	07/04/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
A27	01/03/2022	21/03/2022	25/04/2022	29/04/2022	05/05/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
A28	05/04/2022	25/04/2022	30/05/2022	03/06/2022	10/06/2022	09/06/2022	13/06/2022	16/06/2022	23/06/2022
A29	03/05/2022	23/05/2022	27/06/2022	01/07/2022	07/07/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
A30									
A31	28/06/2022	18/07/2022	22/08/2022	26/08/2022	01/09/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
A32	26/07/2022	15/08/2022	19/09/2022	23/09/2022	29/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
A33	23/08/2022	12/09/2022	17/10/2022	21/10/2022	27/10/2022	27/10/2022	28/10/2022	03/11/2022	10/11/2022
A34	27/09/2022	17/10/2022	21/11/2022	25/11/2022	01/12/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
A35	08/11/2022	28/11/2022	03/01/2023	06/01/2023	12/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
A36	29/11/2022	26/12/2022	30/01/2023	03/02/2023	09/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
A37	10/01/2023	30/01/2023	06/03/2023	10/03/2023	16/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
A38	06/02/2023	26/02/2023	03/04/2023	05/04/2023	14/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
A39	07/03/2023	27/03/2023	02/05/2023	05/05/2023	12/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
A40	04/04/2023	24/04/2023	30/05/2023	02/06/2023	08/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
A41	02/05/2023	22/05/2023	26/06/2023	30/06/2023	06/07/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
A42									
A43	27/06/2023	17/07/2023	21/08/2023	25/08/2023	31/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
A44	25/07/2023	14/08/2023	18/09/2023	22/09/2023	28/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
A45	22/08/2023	11/09/2023	16/10/2023	20/10/2023	26/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
A46	26/09/2023	16/10/2023	20/11/2023	24/11/2023	30/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
A47	07/11/2023	27/11/2023	03/01/2024	05/01/2024	11/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
A48	28/11/2023	25/12/2023	29/01/2024	02/02/2024	08/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
A49	03/01/2024	22/01/2024	26/02/2024	01/03/2024	07/03/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024
A50	06/02/2024	26/02/2024	02/04/2024	05/04/2024	11/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024
A51	12/03/2024	01/04/2024	06/05/2024	08/05/2024	16/05/2024	16/05/2024	17/05/2024	23/05/2024	30/05/2024
A52	09/04/2024	29/04/2024	03/06/2024	07/06/2024	13/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024

	Deadline for Submission (*)	Start (^)	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (˘)	Comments from PRAC (**) (˘)	PRAC outcome (˘) (#)	Updated PRAC Rapporteur AR (˘) (***)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	List of Questions (LoQ) or Opinion
A53	07/05/2024	27/05/2024	01/07/2024	05/07/2024	11/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024
A54									
A55	02/07/2024	22/07/2024	26/08/2024	30/08/2024	05/09/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
A56	30/07/2024	19/08/2024	23/09/2024	27/09/2024	03/10/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
A57	27/08/2024	16/09/2024	21/10/2024	25/10/2024	31/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
A58	24/09/2024	14/10/2024	18/11/2024	22/11/2024	28/11/2024	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.

(^) The validation period between submission date and start date is generally thirteen EMA working days. For further information about the dates on which the Agency will be closed during the current year, please refer to the business hours and holidays page on the website.

(˘) PRAC steps are applicable only if RMP is submitted.

(**) Comments from CHMP and PRAC members are not made available to Applicants.

(#) The PRAC outcome is captured in the subsequent PRAC Rapporteur updated assessment report.

(***) 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 List of Questions (LOQ)

60-day timetable after clock-stop for responses

	Deadline for Submission (*)	Restart	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (~)	Comments from PRAC (**) (~)	PRAC outcome (~) (#)	Updated PRAC Rapporteur AR (~) (***)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	List of Outstanding Issues (LoOI) or Opinion
B1	24/01/2020	27/01/2020	02/03/2020	06/03/2020	12/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
B2	28/02/2020	02/03/2020	06/04/2020	08/04/2020	17/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
B3	27/03/2020	30/03/2020	04/05/2020	08/05/2020	14/05/2020	14/05/2020	18/05/2020	20/05/2020	28/05/2020
B4	24/04/2020	27/04/2020	01/06/2020	05/06/2020	11/06/2020	11/06/2020	15/06/2020	18/06/2020	25/06/2020
B5	22/05/2020	25/05/2020	29/06/2020	03/07/2020	09/07/2020	09/07/2020	13/07/2020	16/07/2020	23/07/2020
B6									
B7	17/07/2020	20/07/2020	24/08/2020	28/08/2020	04/09/2020	04/09/2020	07/09/2020	10/09/2020	17/09/2020
B8	14/08/2020	17/08/2020	21/09/2020	25/09/2020	01/10/2020	01/10/2020	05/10/2020	08/10/2020	15/10/2020
B9	11/09/2020	14/09/2020	19/10/2020	23/10/2020	29/10/2020	29/10/2020	03/11/2020	05/11/2020	12/11/2020
B10	09/10/2020	12/10/2020	16/11/2020	20/11/2020	26/11/2020	26/11/2020	30/11/2020	03/12/2020	10/12/2020
B11	27/11/2020	30/11/2020	04/01/2021	08/01/2021	14/01/2021	14/01/2021	18/01/2021	21/01/2021	28/01/2021
B12	23/12/2020	28/12/2020	01/02/2021	05/02/2021	11/02/2021	11/02/2021	15/02/2021	18/02/2021	25/02/2021
B13	22/01/2021	25/01/2021	01/03/2021	05/03/2021	11/03/2021	11/03/2021	15/03/2021	18/03/2021	25/03/2021
B14	19/02/2021	22/02/2021	29/03/2021	02/04/2021	09/04/2021	09/04/2021	12/04/2021	15/04/2021	22/04/2021
B15	19/03/2021	22/03/2021	26/04/2021	30/04/2021	06/05/2021	06/05/2021	10/05/2021	12/05/2021	20/05/2021
B16	23/04/2021	26/04/2021	31/05/2021	04/06/2021	10/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
B17	21/05/2021	24/05/2021	28/06/2021	02/07/2021	08/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
B18									
B19	16/07/2021	19/07/2021	23/08/2021	27/08/2021	03/09/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
B20	13/08/2021	16/08/2021	20/09/2021	24/09/2021	30/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
B21	10/09/2021	13/09/2021	18/10/2021	22/10/2021	28/10/2021	28/10/2021	29/10/2021	04/11/2021	11/11/2021
B22	15/10/2021	18/10/2021	22/11/2021	26/11/2021	02/12/2021	02/12/2021	06/12/2021	09/12/2021	16/12/2021
B23	26/11/2021	29/11/2021	03/01/2022	07/01/2022	13/01/2022	13/01/2022	17/01/2022	20/01/2022	27/01/2022
B24	22/12/2021	27/12/2021	31/01/2022	04/02/2022	10/02/2022	10/02/2022	14/02/2022	17/02/2022	24/02/2022
B25	21/01/2022	24/01/2022	28/02/2022	04/03/2022	10/03/2022	10/03/2022	14/03/2022	17/03/2022	24/03/2022

	Deadline for Submission (*)	Restart	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (~)	Comments from PRAC (**) (~)	PRAC outcome (~) (#)	Updated PRAC Rapporteur AR (~) (***)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	List of Outstanding Issues (LoOI) or Opinion
B26	18/02/2022	22/02/2022	28/03/2022	01/04/2022	07/04/2022	07/04/2022	11/04/2022	13/04/2022	22/04/2022
B27	18/03/2022	21/03/2022	25/04/2022	29/04/2022	05/05/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
B28	22/04/2022	25/04/2022	30/05/2022	03/06/2022	10/06/2022	10/06/2022	13/06/2022	16/06/2022	23/06/2022
B29	20/05/2022	23/05/2022	27/06/2022	01/07/2022	07/07/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
B30									
B31	15/07/2022	18/07/2022	22/08/2022	26/08/2022	01/09/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
B32	12/08/2022	15/08/2022	19/09/2022	23/09/2022	29/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
B33	09/09/2022	12/09/2022	17/10/2022	21/10/2022	27/10/2022	27/10/2022	28/10/2022	03/11/2022	10/11/2022
B34	14/10/2022	17/10/2022	21/11/2022	25/11/2022	01/12/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
B35	25/11/2022	28/11/2022	03/01/2023	06/01/2023	12/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
B36	22/12/2022	26/12/2022	30/01/2023	03/02/2023	09/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
B37	27/01/2023	30/01/2023	06/03/2023	10/03/2023	16/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
B38	23/02/2023	26/02/2023	03/04/2023	05/04/2023	14/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
B39	24/03/2023	27/03/2023	02/05/2023	05/05/2023	12/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
B40	21/04/2023	24/04/2023	30/05/2023	02/06/2023	08/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
B41	17/05/2023	22/05/2023	26/06/2023	30/06/2023	06/07/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
B42									
B43	14/07/2023	17/07/2023	21/08/2023	25/08/2023	31/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
B44	11/08/2023	14/08/2023	18/09/2023	22/09/2023	28/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
B45	08/09/2023	11/09/2023	16/10/2023	20/10/2023	26/10/2023	26/10/2023	27/10/2023	31/10/2023	09/11/2023
B46	13/10/2023	16/10/2023	20/11/2023	24/11/2023	30/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
B47	24/11/2023	27/11/2023	03/01/2024	05/01/2024	11/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
B48	21/12/2023	25/12/2023	29/01/2024	02/02/2024	08/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
B49	19/01/2024	22/01/2024	26/02/2024	01/03/2024	07/03/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024
B50	23/02/2024	26/02/2024	02/04/2024	05/04/2024	11/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024
B51	27/03/2024	01/04/2024	06/05/2024	08/05/2024	16/05/2024	16/05/2024	17/05/2024	23/05/2024	30/05/2024
B52	26/04/2024	29/04/2024	03/06/2024	07/06/2024	13/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024
B53	24/05/2024	27/05/2024	01/07/2024	05/07/2024	11/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024

	Deadline for Submission (*)	Restart	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (~)	Comments from PRAC (**) (~)	PRAC outcome (~) (#)	Updated PRAC Rapporteur AR (~) (***)	Comments from CHMP (**)	Updated CHMP Rapporteur AR (***)	List of Outstanding Issues (LoOI) or Opinion
B54									
B55	19/07/2024	22/07/2024	26/08/2024	30/08/2024	05/09/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
B56	16/08/2024	19/08/2024	23/09/2024	27/09/2024	03/10/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
B57	13/09/2024	16/09/2024	21/10/2024	25/10/2024	31/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
B58	11/10/2024	14/10/2024	18/11/2024	22/11/2024	28/11/2024	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.

(~) PRAC steps are applicable only if RMP is submitted.

(**) Comments from CHMP and PRAC members are not made available to Applicants.

(#) The PRAC outcome is captured in the subsequent PRAC Rapporteur updated assessment report.

(***) 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 List of Outstanding Issues (LoOI)

30-day timetable after clock-stop for responses

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

	Deadline for Submission (*)	Restart	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (~)	Comments from (PRAC and) CHMP (**) (~)	Updated (PRAC and) CHMP Rapporteur(s) Joint) AR (JAR) (~) (#) (***)	Opinion
C40	25/04/2023	26/04/2023	10/05/2023	15/05/2023	17/05/2023	25/05/2023
C41	23/05/2023	24/05/2023	07/06/2023	12/06/2023	15/06/2023	22/06/2023
C42	20/06/2023	21/06/2023	05/07/2023	10/07/2023	13/07/2023	20/07/2023
C43						
C44	14/08/2023	16/08/2023	30/08/2023	04/09/2023	07/09/2023	14/09/2023
C45	12/09/2023	13/09/2023	27/09/2023	02/10/2023	05/10/2023	12/10/2023
C46	10/10/2023	11/10/2023	25/10/2023	30/10/2023	31/10/2023	09/11/2023
C47	14/11/2023	15/11/2023	29/11/2023	04/12/2023	07/12/2023	14/12/2023
C48	21/12/2023	27/12/2023	10/01/2024	15/01/2024	18/01/2024	25/01/2024
C49	23/01/2024	24/01/2024	07/02/2024	12/02/2024	15/02/2024	22/02/2024
C50	20/02/2024	21/02/2024	06/03/2024	11/03/2024	14/03/2024	21/03/2024
C51	26/03/2024	27/03/2024	10/04/2024	15/04/2024	18/04/2024	25/04/2024
C52	30/04/2024	01/05/2024	15/05/2024	21/05/2024	23/05/2024	30/05/2024
C53	28/05/2024	29/05/2024	12/06/2024	17/06/2024	20/06/2024	27/06/2024
C54	25/06/2024	26/06/2024	10/07/2024	15/07/2024	18/07/2024	25/07/2024
C55						
C56	20/08/2024	21/08/2024	04/09/2024	09/09/2024	12/09/2024	19/09/2024
C57	17/09/2024	18/09/2024	02/10/2024	07/10/2024	10/10/2024	17/10/2024
C58	15/10/2024	16/10/2024	30/10/2024	04/11/2024	07/11/2024	14/11/2024
C59	12/11/2024	13/11/2024	27/11/2024	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.

(~) PRAC steps are applicable only if RMP is submitted.

(#) A PRAC discussion is not foreseen for a 30-day timetable; PRAC member comments are reflected in the subsequent updated PRAC Rapporteur's AR.

(**) Comments from CHMP and PRAC members are not made available to Applicants.

(***) 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 List of Outstanding Issues (LoOI)

30-day timetable after immediate responses

	Deadline for Submission (*)	Restart	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (~)	Comments from (PRAC and) CHMP (**) (~)	Updated (PRAC and) CHMP Rapporteur(s) Joint) AR (JAR) (~) (#) (***)	Opinion
D1	07/01/2020	08/01/2020	15/01/2020	20/01/2020	23/01/2020	30/01/2020
D2	04/02/2020	05/02/2020	12/02/2020	17/02/2020	20/02/2020	27/02/2020
D3	03/03/2020	04/03/2020	11/03/2020	16/03/2020	19/03/2020	26/03/2020
D4	02/04/2020	03/04/2020	15/04/2020	20/04/2020	23/04/2020	30/04/2020
D5	05/05/2020	06/05/2020	13/05/2020	18/05/2020	20/05/2020	28/05/2020
D6	02/06/2020	03/06/2020	10/06/2020	15/06/2020	18/06/2020	25/06/2020
D7	30/06/2020	01/07/2020	08/07/2020	13/07/2020	16/07/2020	23/07/2020
D8						
D9	25/08/2020	26/08/2020	02/09/2020	07/09/2020	10/09/2020	17/09/2020
D10	22/09/2020	23/09/2020	30/09/2020	05/10/2020	08/10/2020	15/10/2020
D11	20/10/2020	21/10/2020	28/10/2020	03/11/2020	05/11/2020	12/11/2020
D12	17/11/2020	18/11/2020	25/11/2020	30/11/2020	03/12/2020	10/12/2020
D13	23/12/2020	30/12/2020	13/01/2021	18/01/2021	21/01/2021	28/01/2021
D14	02/02/2021	03/02/2021	10/02/2021	15/02/2021	18/02/2021	25/02/2021
D15	02/03/2021	03/03/2021	10/03/2021	15/03/2021	18/03/2021	25/03/2021
D16	30/03/2021	31/03/2021	07/04/2021	12/04/2021	15/04/2021	22/04/2021
D17	27/04/2021	28/04/2021	05/05/2021	10/05/2021	12/05/2021	20/05/2021
D18	27/05/2021	28/05/2021	09/06/2021	14/06/2021	17/06/2021	24/06/2021
D19	29/06/2021	30/06/2021	07/07/2021	12/07/2021	15/07/2021	22/07/2021
D20						
D21	24/08/2021	25/08/2021	01/09/2021	06/09/2021	09/09/2021	16/09/2021
D22	21/09/2021	22/09/2021	29/09/2021	04/10/2021	07/10/2021	14/10/2021
D23	19/10/2021	20/10/2021	27/10/2021	03/11/2021	05/11/2021	11/11/2021
D24	18/11/2021	19/11/2021	01/12/2021	06/12/2021	09/12/2021	16/12/2021
D25	22/12/2021	29/12/2021	12/01/2022	17/01/2022	20/01/2022	27/01/2022
D26	01/02/2022	02/02/2022	09/02/2022	14/02/2022	17/02/2022	24/02/2022
D27	01/03/2022	02/03/2022	09/03/2022	14/03/2022	17/03/2022	24/03/2022
D28	30/03/2022	31/03/2022	06/04/2022	11/04/2022	13/04/2022	22/04/2022
D29	26/04/2022	27/04/2022	04/05/2022	10/05/2022	12/05/2022	19/05/2022
D30	25/05/2022	27/05/2022	08/06/2022	13/06/2022	16/06/2022	23/06/2022
D31	28/06/2022	29/06/2022	06/07/2022	11/07/2022	14/07/2022	21/07/2022
D32						
D33	16/08/2022	17/08/2022	31/08/2022	05/09/2022	08/09/2022	15/09/2022
D34	20/09/2022	21/09/2022	28/09/2022	03/10/2022	06/10/2022	13/10/2022
D35	18/10/2022	19/10/2022	26/10/2022	28/10/2022	03/11/2022	10/11/2022
D36	16/11/2022	18/11/2022	30/11/2022	05/12/2022	08/12/2022	15/12/2022
D37	22/12/2022	28/12/2022	11/01/2023	16/01/2023	19/01/2023	26/01/2023
D38	31/01/2023	01/02/2023	08/02/2023	13/02/2023	16/02/2023	23/02/2023
D39	28/02/2023	01/03/2023	15/03/2023	20/03/2023	23/03/2023	30/03/2023

	Deadline for Submission (*)	Restart	CHMP (and PRAC) Rapporteur(s) Joint) AR (JAR) (~)	Comments from (PRAC and) CHMP (**) (~)	Updated (PRAC and) CHMP Rapporteur(s) Joint) AR (JAR) (~) (#) (***)	Opinion
D40	03/04/2023	04/04/2023	12/04/2023	17/04/2023	20/04/2023	26/04/2023
D41	02/05/2023	03/05/2023	10/05/2023	15/05/2023	17/05/2023	25/05/2023
D42	30/05/2023	31/05/2023	07/06/2023	12/06/2023	15/06/2023	22/06/2023
D43	27/06/2023	28/06/2023	05/07/2023	10/07/2023	13/07/2023	20/07/2023
D44						
D45	14/08/2023	16/08/2023	30/08/2023	04/09/2023	07/09/2023	14/09/2023
D46	19/09/2023	20/09/2023	27/09/2023	02/10/2023	05/10/2023	12/10/2023
D47	17/10/2023	18/10/2023	25/10/2023	30/10/2023	31/10/2023	09/11/2023
D48	16/11/2023	17/11/2023	29/11/2023	04/12/2023	07/12/2023	14/12/2023
D49	21/12/2023	27/12/2023	10/01/2024	15/01/2024	18/01/2024	25/01/2024
D50	30/01/2024	31/01/2024	07/02/2024	12/02/2024	15/02/2024	22/02/2024
D51	27/02/2024	28/02/2024	06/03/2024	11/03/2024	14/03/2024	21/03/2024
D52	27/03/2024	29/03/2024	10/04/2024	15/04/2024	18/04/2024	25/04/2024
D53	02/05/2024	03/05/2024	15/05/2024	21/05/2024	23/05/2024	30/05/2024
D54	04/06/2024	05/06/2024	12/06/2024	17/06/2024	20/06/2024	27/06/2024
D55	02/07/2024	03/07/2024	10/07/2024	15/07/2024	18/07/2024	25/07/2024
D56						
D57	20/08/2024	21/08/2024	04/09/2024	09/09/2024	12/09/2024	19/09/2024
D58	24/09/2024	25/09/2024	02/10/2024	07/10/2024	10/10/2024	17/10/2024
D59	22/10/2024	23/10/2024	30/10/2024	04/11/2024	07/11/2024	14/11/2024
D60	19/11/2024	20/11/2024	27/11/2024	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.

(~) PRAC steps are applicable only if RMP is submitted.

(#) A PRAC discussion is not foreseen for a 30-day timetable; PRAC member comments are reflected in the subsequent updated PRAC Rapporteur's AR.

(**) Comments from CHMP and PRAC members are not made available to Applicants.

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