



2 June 2021  
EMA/119185/2015 Rev.9  
Human Medicines Division

The timetables in this document may be subject to revision

## Initial (Full) Marketing Authorisation application assessment timetables

[Assessment of initial submission \(120-day timetable\)](#)

[Assessment of responses to List of Questions \(60-day timetable after clock-stop for submission of responses\)](#)

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

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

[Assessment of Outstanding Issues following Oral Explanation \(30-day timetable\)](#)

## Assessment of initial submission (120-day timetable)

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

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs (***)	PRAC Rapporteur AR and CHMP Co-Rapporteur critique (***)	Comments from PRAC (**)	Comments from CHMP (**)	Early draft LOQ (for Peer review tele-conference) (#)	PRAC outcome (~)	Updated PRAC Rapporteur AR	Peer review telecon-ference (TC)	Draft LoQ	List of Questions (LoQ) or Opinion
A25	03/01/2022	20/01/2022	11/04/2022	25/04/2022	29/04/2022	29/04/2022	05/05/2022	05/05/2022	05/05/2022	10/05/2022	12/05/2022	19/05/2022
A26	07/02/2022	24/02/2022	16/05/2022	30/05/2022	03/06/2022	03/06/2022	10/06/2022	10/06/2022	10/06/2022	13/06/2022	16/06/2022	23/06/2022
A27	07/03/2022	24/03/2022	13/06/2022	27/06/2022	01/07/2022	01/07/2022	07/07/2022	07/07/2022	07/07/2022	11/07/2022	14/07/2022	21/07/2022
A28												
A29	02/05/2022	19/05/2022	08/08/2022	22/08/2022	26/08/2022	26/08/2022	01/09/2022	01/09/2022	01/09/2022	05/09/2022	08/09/2022	15/09/2022
A30	30/05/2022	16/06/2022	05/09/2022	19/09/2022	23/09/2022	23/09/2022	29/09/2022	29/09/2022	29/09/2022	03/10/2022	06/10/2022	13/10/2022
A31	27/06/2022	14/07/2022	03/10/2022	17/10/2022	21/10/2022	21/10/2022	27/10/2022	27/10/2022	27/10/2022	28/10/2022	03/11/2022	10/11/2022
A32	01/08/2022	18/08/2022	07/11/2022	21/11/2022	25/11/2022	25/11/2022	01/12/2022	01/12/2022	01/12/2022	05/12/2022	08/12/2022	15/12/2022
A33	12/09/2022	29/09/2022	19/12/2022	03/01/2023	06/01/2023	06/01/2023	12/01/2023	12/01/2023	12/01/2023	16/01/2023	19/01/2023	26/01/2023
A34	10/10/2022	27/10/2022	16/01/2023	30/01/2023	03/02/2023	03/02/2023	09/02/2023	09/02/2023	09/02/2023	13/02/2023	16/02/2023	23/02/2023
A35	14/11/2022	01/12/2022	20/02/2023	06/03/2023	10/03/2023	10/03/2023	16/03/2023	16/03/2023	16/03/2023	20/03/2023	23/03/2023	30/03/2023
A36	28/11/2022	28/12/2022	20/03/2023	03/04/2023	05/04/2023	05/04/2023	14/04/2023	14/04/2023	14/04/2023	17/04/2023	20/04/2023	26/04/2023
A37	09/01/2023	26/01/2023	17/04/2023	02/05/2023	05/05/2023	05/05/2023	12/05/2023	12/05/2023	12/05/2023	15/05/2023	17/05/2023	25/05/2023
A38	06/02/2023	23/02/2023	15/05/2023	30/05/2023	02/06/2023	02/06/2023	08/06/2023	08/06/2023	08/06/2023	12/06/2023	15/06/2023	22/06/2023
A39	06/03/2023	23/03/2023	12/06/2023	26/06/2023	30/06/2023	30/06/2023	06/07/2023	06/07/2023	06/07/2023	10/07/2023	13/07/2023	20/07/2023
A40												
A41	26/04/2023	18/05/2023	07/08/2023	21/08/2023	25/08/2023	25/08/2023	31/08/2023	31/08/2023	31/08/2023	04/09/2023	07/09/2023	14/09/2023
A42	26/05/2023	15/06/2023	04/09/2023	18/09/2023	22/09/2023	22/09/2023	28/09/2023	28/09/2023	28/09/2023	02/10/2023	05/10/2023	12/10/2023
A43	26/06/2023	13/07/2023	02/10/2023	16/10/2023	20/10/2023	20/10/2023	26/10/2023	26/10/2023	26/10/2023	30/10/2023	31/10/2023	09/11/2023
A44	31/07/2023	17/08/2023	06/11/2023	20/11/2023	24/11/2023	24/11/2023	30/11/2023	30/11/2023	30/11/2023	04/12/2023	07/12/2023	14/12/2023
A45	11/09/2023	28/09/2023	18/12/2023	03/01/2024	05/01/2024	05/01/2024	11/01/2024	11/01/2024	11/01/2024	15/01/2024	18/01/2024	25/01/2024
A46	09/10/2023	26/10/2023	15/01/2024	29/01/2024	02/02/2024	02/02/2024	08/02/2024	08/02/2024	08/02/2024	12/02/2024	15/02/2024	22/02/2024
A47	06/11/2023	23/11/2023	12/02/2024	26/02/2024	01/03/2024	01/03/2024	07/03/2024	07/03/2024	07/03/2024	11/03/2024	14/03/2024	21/03/2024
A48	27/11/2023	28/12/2023	18/03/2024	02/04/2024	05/04/2024	05/04/2024	11/04/2024	11/04/2024	11/04/2024	15/04/2024	18/04/2024	25/04/2024
A49	15/01/2024	01/02/2024	22/04/2024	06/05/2024	08/05/2024	08/05/2024	16/05/2024	16/05/2024	16/05/2024	21/05/2024	23/05/2024	30/05/2024
A50	12/02/2024	29/02/2024	21/05/2024	03/06/2024	07/06/2024	07/06/2024	13/06/2024	13/06/2024	13/06/2024	17/06/2024	20/06/2024	27/06/2024

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs (***)	PRAC Rapporteur AR and CHMP Co-Rapporteur critique (***)	Comments from PRAC (**)	Comments from CHMP (**)	Early draft LOQ (for Peer review tele-conference) (#)	PRAC outcome (~)	Updated PRAC Rapporteur AR	Peer review telecon-ference (TC)	Draft LoQ	List of Questions (LoQ) or Opinion
A51	11/03/2024	28/03/2024	17/06/2024	01/07/2024	05/07/2024	05/07/2024	11/07/2024	11/07/2024	11/07/2024	15/07/2024	18/07/2024	25/07/2024
A52												
A53	30/04/2024	23/05/2024	12/08/2024	26/08/2024	30/08/2024	30/08/2024	05/09/2024	05/09/2024	05/09/2024	09/09/2024	12/09/2024	19/09/2024
A54	03/06/2024	20/06/2024	09/09/2024	23/09/2024	27/09/2024	27/09/2024	03/10/2024	03/10/2024	03/10/2024	07/10/2024	10/10/2024	17/10/2024
A55	01/07/2024	18/07/2024	07/10/2024	21/10/2024	25/10/2024	25/10/2024	31/10/2024	31/10/2024	31/10/2024	04/11/2024	07/11/2024	14/11/2024
A56	29/07/2024	15/08/2024	04/11/2024	18/11/2024	22/11/2024	22/11/2024	28/11/2024	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.

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

(#) Peer review is a process by which other members of the CHMP review the (Co) Rapporteurs' scientific evaluation, as well as the validity of the scientific/regulatory conclusions reached. It applies during the initial phase of the assessment of a new Marketing Authorisation Application (MAA).

(~) PRAC discussion (and outcome) during the 1st assessment phase is only envisaged for a minority of applications.

(\*\*\*) When involved, the CHMP Co-Rapporteur produces a critique on the CHMP AR for non-COVID 19 related applications. The Rapporteur AR and Co-Rapporteur critique will be both made available to the applicant.

## Assessment of responses to List of Questions (LOQ)

60-day timetable after clock-stop for submission of responses

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC (**)	PRAC outcome (#)	Updated PRAC Rapporteur AR	Comments from CHMP (**)	Updated CHMP (and PRAC) Rapporteurs JAR (~)	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

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC (**)	PRAC outcome (#)	Updated PRAC Rapporteur AR	Comments from CHMP (**)	Updated CHMP (and PRAC) Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) or Opinion
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
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

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC (**)	PRAC outcome (#)	Updated PRAC Rapporteur AR	Comments from CHMP (**)	Updated CHMP (and PRAC) Rapporteurs JAR (~)	List of Outstanding Issues (LoOI) or Opinion
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
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.

(\*\*) 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.

(~) This assessment report incorporates the PRAC Rapporteur updated assessment report circulated earlier at the conclusion of the PRAC meeting.

# Assessment of responses to List of Outstanding Issues (LoOI)

30-day timetable after clock-stop for responses

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs 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	03/11/2022	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 Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs 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.

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

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

# Assessment of responses to List of Outstanding Issues (LoOI)

30-day timetable after immediate responses<sup>#</sup>

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	Opinion
D1	23/12/2019	01/01/2020	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 Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs 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

(#) This timetable is only used exceptionally and after agreement with the Rapporteurs when minor issues remain which allow the applicant to respond shortly after the CHMP list of questions and the Rapporteurs to assess the responses within a shortened assessment time.

(\*) 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 and PRAC members are not made available to Applicants.

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

# Assessment of Outstanding Issues following Oral Explanation

## 30-day timetable<sup>#</sup>

	Restart	(PRAC and) CHMP Rapporteurs Joint AR (JAR) (*)	Comments from (PRAC and) CHMP on JAR (**)	Updated (PRAC and) CHMP Rapporteurs JAR	Opinion
E1	08/01/2020	15/01/2020	20/01/2020	23/01/2020	30/01/2020
E2	05/02/2020	12/02/2020	17/02/2020	20/02/2020	27/02/2020
E3	04/03/2020	11/03/2020	16/03/2020	19/03/2020	26/03/2020
E4	08/04/2020	15/04/2020	20/04/2020	23/04/2020	30/04/2020
E5	06/05/2020	13/05/2020	18/05/2020	20/05/2020	28/05/2020
E6	03/06/2020	10/06/2020	15/06/2020	18/06/2020	25/06/2020
E7	01/07/2020	08/07/2020	13/07/2020	16/07/2020	23/07/2020
E8					
E9	26/08/2020	02/09/2020	07/09/2020	10/09/2020	17/09/2020
E10	23/09/2020	30/09/2020	05/10/2020	08/10/2020	15/10/2020
E11	21/10/2020	28/10/2020	03/11/2020	05/11/2020	12/11/2020
E12	18/11/2020	25/11/2020	30/11/2020	03/12/2020	10/12/2020
E13	06/01/2021	13/01/2021	18/01/2021	21/01/2021	28/01/2021
E14	03/02/2021	10/02/2021	15/02/2021	18/02/2021	25/02/2021
E15	03/03/2021	10/03/2021	15/03/2021	18/03/2021	25/03/2021
E16	31/03/2021	07/04/2021	12/04/2021	15/04/2021	22/04/2021
E17	28/04/2021	05/05/2021	10/05/2021	12/05/2021	20/05/2021
E18	02/06/2021	09/06/2021	14/06/2021	17/06/2021	24/06/2021
E19	30/06/2021	07/07/2021	12/07/2021	15/07/2021	22/07/2021
E20					
E21	25/08/2021	01/09/2021	06/09/2021	09/09/2021	16/09/2021
E22	22/09/2021	29/09/2021	04/10/2021	07/10/2021	14/10/2021
E23	20/10/2021	27/10/2021	03/11/2021	05/11/2021	11/11/2021
E24	24/11/2021	01/12/2021	06/12/2021	09/12/2021	16/12/2021
E25	29/12/2021	12/01/2022	17/01/2022	20/01/2022	27/01/2022
E26	02/02/2022	09/02/2022	14/02/2022	17/02/2022	24/02/2022
E27	02/03/2022	09/03/2022	14/03/2022	17/03/2022	24/03/2022
E28	31/03/2022	06/04/2022	11/04/2022	13/04/2022	22/04/2022
E29	27/04/2022	04/05/2022	10/05/2022	12/05/2022	19/05/2022
E30	27/05/2022	08/06/2022	13/06/2022	16/06/2022	23/06/2022
E31	29/06/2022	06/07/2022	11/07/2022	14/07/2022	21/07/2022
E32					
E33	17/08/2022	31/08/2022	05/09/2022	08/09/2022	15/09/2022
E34	21/09/2022	28/09/2022	03/10/2022	06/10/2022	13/10/2022
E35	19/10/2022	26/10/2022	28/10/2022	03/11/2022	10/11/2022
E36	18/11/2022	30/11/2022	05/12/2022	08/12/2022	15/12/2022
E37	28/12/2022	11/01/2023	16/01/2023	19/01/2023	26/01/2023
E38	01/02/2023	08/02/2023	13/02/2023	16/02/2023	23/02/2023
E39	01/03/2023	15/03/2023	20/03/2023	23/03/2023	30/03/2023

	Restart	(PRAC and) CHMP Rapporteurs Joint AR (JAR) (*)	Comments from (PRAC and) CHMP on JAR (**)	Updated (PRAC and) CHMP Rapporteurs JAR	Opinion
E40	04/04/2023	12/04/2023	17/04/2023	20/04/2023	26/04/2023
E41	03/05/2023	10/05/2023	15/05/2023	17/05/2023	25/05/2023
E42	31/05/2023	07/06/2023	12/06/2023	15/06/2023	22/06/2023
E43	28/06/2023	05/07/2023	10/07/2023	13/07/2023	20/07/2023
E44					
E45	16/08/2023	30/08/2023	04/09/2023	07/09/2023	14/09/2023
E46	20/09/2023	27/09/2023	02/10/2023	05/10/2023	12/10/2023
E47	18/10/2023	25/10/2023	30/10/2023	31/10/2023	09/11/2023
E48	17/11/2023	29/11/2023	04/12/2023	07/12/2023	14/12/2023
E49	27/12/2023	10/01/2024	15/01/2024	18/01/2024	25/01/2024
E50	31/01/2024	07/02/2024	12/02/2024	15/02/2024	22/02/2024
E51	28/02/2024	06/03/2024	11/03/2024	14/03/2024	21/03/2024
E52	29/03/2024	10/04/2024	15/04/2024	18/04/2024	25/04/2024
E53	03/05/2024	15/05/2024	21/05/2024	23/05/2024	30/05/2024
E54	05/06/2024	12/06/2024	17/06/2024	20/06/2024	27/06/2024
E55	03/07/2024	10/07/2024	15/07/2024	18/07/2024	25/07/2024
E56					
E57	21/08/2024	04/09/2024	09/09/2024	12/09/2024	19/09/2024
E58	25/09/2024	02/10/2024	07/10/2024	10/10/2024	17/10/2024
E59	23/10/2024	30/10/2024	04/11/2024	07/11/2024	14/11/2024
E60	20/11/2024	27/11/2024	02/12/2024	05/12/2024	12/12/2024

(#) This timetable is used when minor issues, most commonly but not exclusively related to the Product Information and the Risk Management Plan, remain after an Oral Explanation.

(\*) The involvement of CHMP and PRAC Rapporteurs in this assessment phase depends on the nature of the remaining issues and it could be optional for the PRAC Rapporteur.

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