

31 October 2017
EMA/119185/2015 Rev.5
Human Medicines Evaluation

[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	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	02/01/2017	19/01/2017	08/04/2017	21/04/2017	28/04/2017	28/04/2017	05/05/2017	05/05/2017	05/05/2017	08/05/2017	11/05/2017	18/05/2017
A2	06/02/2017	23/02/2017	13/05/2017	29/05/2017	02/06/2017	02/06/2017	09/06/2017	09/06/2017	09/06/2017	12/06/2017	15/06/2017	22/06/2017
A3	06/03/2017	23/03/2017	10/06/2017	23/06/2017	30/06/2017	30/06/2017	06/07/2017	06/07/2017	06/07/2017	10/07/2017	13/07/2017	20/07/2017
A4												
A5	27/04/2017	18/05/2017	05/08/2017	18/08/2017	25/08/2017	25/08/2017	01/09/2017	01/09/2017	01/09/2017	04/09/2017	07/09/2017	14/09/2017
A6	24/05/2017	15/06/2017	02/09/2017	15/09/2017	22/09/2017	22/09/2017	28/09/2017	28/09/2017	28/09/2017	02/10/2017	05/10/2017	12/10/2017
A7	26/06/2017	13/07/2017	30/09/2017	13/10/2017	20/10/2017	20/10/2017	26/10/2017	26/10/2017	26/10/2017	30/10/2017	03/11/2017	09/11/2017
A8	31/07/2017	17/08/2017	04/11/2017	17/11/2017	24/11/2017	24/11/2017	30/11/2017	30/11/2017	30/11/2017	04/12/2017	07/12/2017	14/12/2017
A9	11/09/2017	28/09/2017	16/12/2017	03/01/2018	05/01/2018	05/01/2018	11/01/2018	11/01/2018	11/01/2018	15/01/2018	18/01/2018	25/01/2018
A10	09/10/2017	26/10/2017	15/01/2018	26/01/2018	02/02/2018	02/02/2018	08/02/2018	08/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
A11	06/11/2017	23/11/2017	12/02/2018	26/02/2018	02/03/2018	02/03/2018	08/03/2018	08/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
A12	27/11/2017	28/12/2017	19/03/2018	03/04/2018	06/04/2018	06/04/2018	12/04/2018	12/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
A13	15/01/2018	01/02/2018	23/04/2018	07/05/2018	11/05/2018	11/05/2018	17/05/2018	17/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
A14	12/02/2018	01/03/2018	22/05/2018	04/06/2018	08/06/2018	08/06/2018	14/06/2018	14/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
A15	08/03/2018	29/03/2018	18/06/2018	02/07/2018	06/07/2018	06/07/2018	12/07/2018	12/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
A16												
A17	30/04/2018	24/05/2018	13/08/2018	28/08/2018	31/08/2018	31/08/2018	06/09/2018	06/09/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
A18	04/06/2018	21/06/2018	10/09/2018	24/09/2018	28/09/2018	28/09/2018	04/10/2018	04/10/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
A19	02/07/2018	19/07/2018	08/10/2018	22/10/2018	26/10/2018	26/10/2018	31/10/2018	31/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
A20	30/07/2018	16/08/2018	05/11/2018	19/11/2018	23/11/2018	23/11/2018	29/11/2018	29/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
A21	17/09/2018	04/10/2018	20/12/2018	07/01/2019	11/01/2019	11/01/2019	17/01/2019	17/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019
A22	15/10/2018	01/11/2018	21/01/2019	04/02/2019	08/02/2019	08/02/2019	14/02/2019	14/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019
A23	12/11/2018	29/11/2018	18/02/2019	04/03/2019	08/03/2019	08/03/2019	14/03/2019	14/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019
A24	26/11/2018	28/12/2018	18/03/2019	01/04/2019	05/04/2019	05/04/2019	11/04/2019	11/04/2019	11/04/2019	15/04/2019	17/04/2019	26/04/2019
A25	14/01/2019	30/01/2019	23/04/2019	02/05/2019	10/05/2019	10/05/2019	16/05/2019	16/05/2019	16/05/2019	20/05/2019	23/05/2019	29/05/2019

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs	PRAC Rapporteur AR	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
A26	11/02/2019	28/02/2019	20/05/2019	03/06/2019	07/06/2019	07/06/2019	13/06/2019	14/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
A27	11/03/2019	28/03/2019	17/06/2019	01/07/2019	05/07/2019	05/07/2019	11/07/2019	11/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
A28												
A29	06/05/2019	23/05/2019	12/08/2019	27/08/2019	30/08/2019	30/08/2019	05/09/2019	05/09/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
A30	03/06/2019	20/06/2019	09/09/2019	23/09/2019	27/09/2019	27/09/2019	03/10/2019	03/10/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
A31	01/07/2019	18/07/2019	07/10/2019	21/10/2019	25/10/2019	25/10/2019	31/10/2019	31/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
A33	29/07/2019	15/08/2019	04/11/2019	18/11/2019	22/11/2019	22/11/2019	28/11/2019	28/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
A34	16/09/2019	03/10/2019	19/12/2019	06/01/2020	10/01/2020	10/01/2020	16/01/2020	16/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
A35	14/10/2019	31/10/2019	20/01/2020	03/02/2020	07/02/2020	07/02/2020	13/02/2020	13/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
A36	11/11/2019	28/11/2019	17/02/2020	02/03/2020	06/03/2020	06/03/2020	12/03/2020	12/03/2020	12/03/2020	16/03/2020	19/03/2020	26/03/2020
A37	25/11/2019	02/01/2020	23/03/2020	06/04/2020	08/04/2020	08/04/2020	16/04/2020	17/04/2020	17/04/2020	20/04/2020	23/04/2020	30/04/2020
A38	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
A39	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
A40	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
A41												
A42	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
A43	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
A45	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
A46	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
A47	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
A48	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
A49	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
A50	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
A51	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
A52	08/02/2021	25/02/2021	17/05/2021	31/05/2021	04/06/2021	04/06/2021	10/06/2021	10/06/2021	10/06/2021	14/06/2021	17/06/2021	24/06/2021
A53	08/03/2021	25/03/2021	14/06/2021	28/06/2021	02/07/2021	02/07/2021	08/07/2021	08/07/2021	08/07/2021	12/07/2021	15/07/2021	22/07/2021
A54												

	Deadline for Submission (*)	Start date (^)	CHMP (Co) Rapporteur ARs	PRAC Rapporteur AR	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
A55	30/04/2021	20/05/2021	09/08/2021	23/08/2021	27/08/2021	27/08/2021	02/09/2021	03/09/2021	03/09/2021	06/09/2021	09/09/2021	16/09/2021
A56	31/05/2021	17/06/2021	06/09/2021	20/09/2021	24/09/2021	24/09/2021	30/09/2021	30/09/2021	30/09/2021	04/10/2021	07/10/2021	14/10/2021
A57	28/06/2021	15/07/2021	04/10/2021	18/10/2021	22/10/2021	22/10/2021	27/10/2021	28/10/2021	28/10/2021	29/10/2021	04/11/2021	11/11/2021
A58	02/08/2021	19/08/2021	08/11/2021	22/11/2021	26/11/2021	26/11/2021	02/12/2021	02/12/2021	02/12/2021	06/12/2021	09/12/2021	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.

(^) 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.

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	20/01/2017	23/01/2017	27/02/2017	03/03/2017	09/03/2017	09/03/2017	13/03/2017	16/03/2017	23/03/2017
B2	17/02/2017	21/02/2017	27/03/2017	31/03/2017	06/04/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
B3	17/03/2017	20/03/2017	24/04/2017	28/04/2017	05/05/2017	05/05/2017	08/05/2017	11/05/2017	18/05/2017
B4	21/04/2017	24/04/2017	29/05/2017	02/06/2017	09/06/2017	09/06/2017	12/06/2017	15/06/2017	22/06/2017
B5	19/05/2017	22/05/2017	26/06/2017	30/06/2017	06/07/2017	06/07/2017	10/07/2017	13/07/2017	20/07/2017
B6									
B7	14/07/2017	17/07/2017	21/08/2017	25/08/2017	01/09/2017	01/09/2017	04/09/2017	07/09/2017	14/09/2017
B8	11/08/2017	14/08/2017	18/09/2017	22/09/2017	28/09/2017	28/09/2017	02/10/2017	05/10/2017	12/10/2017
B9	08/09/2017	11/09/2017	16/10/2017	20/10/2017	26/10/2017	26/10/2017	30/10/2017	03/11/2017	09/11/2017
B10	13/10/2017	16/10/2017	20/11/2017	24/11/2017	30/11/2017	30/11/2017	04/12/2017	07/12/2017	14/12/2017
B11	24/11/2017	27/11/2017	03/01/2018	05/01/2018	11/01/2018	11/01/2018	15/01/2018	18/01/2018	25/01/2018
B12	22/12/2017	25/12/2017	29/01/2018	02/02/2018	08/02/2018	08/02/2018	12/02/2018	15/02/2018	22/02/2018
B13	19/01/2018	22/01/2018	26/02/2018	02/03/2018	08/03/2018	08/03/2018	12/03/2018	15/03/2018	22/03/2018
B14	23/02/2018	26/02/2018	03/04/2018	06/04/2018	12/04/2018	12/04/2018	16/04/2018	19/04/2018	26/04/2018
B15	28/03/2018	02/04/2018	04/05/2018	08/05/2018	17/05/2018	17/05/2018	22/05/2018	24/05/2018	31/05/2018
B16	27/04/2018	30/04/2018	04/06/2018	08/06/2018	14/06/2018	14/06/2018	18/06/2018	21/06/2018	28/06/2018
B17	25/05/2018	28/05/2018	02/07/2018	06/07/2018	12/07/2018	12/07/2018	16/07/2018	19/07/2018	26/07/2018
B18									
B19	20/07/2018	23/07/2018	28/08/2018	31/08/2018	06/09/2018	06/09/2018	10/09/2018	13/09/2018	20/09/2018
B20	17/08/2018	20/08/2018	24/09/2018	28/09/2018	04/10/2018	04/10/2018	08/10/2018	11/10/2018	18/10/2018
B21	14/09/2018	17/09/2018	22/10/2018	26/10/2018	31/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
B22	12/10/2018	15/10/2018	19/11/2018	23/11/2018	29/11/2018	29/11/2018	03/12/2018	06/12/2018	13/12/2018
B23	30/11/2018	03/12/2018	07/01/2019	11/01/2019	17/01/2019	17/01/2019	21/01/2019	24/01/2019	31/01/2019

	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
B24	21/12/2018	31/12/2018	04/02/2019	08/02/2019	14/02/2019	14/02/2019	18/02/2019	21/02/2019	28/02/2019
B25	25/01/2019	28/01/2019	04/03/2019	08/03/2019	14/03/2019	14/03/2019	18/03/2019	21/03/2019	28/03/2019
B26	22/02/2019	26/02/2019	01/04/2019	05/04/2019	12/04/2019	12/04/2019	15/04/2019	17/04/2019	26/04/2019
B27	29/03/2019	31/03/2019	06/05/2019	10/05/2019	15/05/2019	15/05/2019	20/05/2019	23/05/2019	29/05/2019
B28	26/04/2019	29/04/2019	03/06/2019	07/06/2019	14/06/2019	14/06/2019	17/06/2019	20/06/2019	27/06/2019
B29	24/05/2019	27/05/2019	01/07/2019	05/07/2019	11/07/2019	11/07/2019	15/07/2019	18/07/2019	25/07/2019
B30									
B31	19/07/2019	22/07/2019	26/08/2019	30/08/2019	05/09/2019	05/09/2019	09/09/2019	12/09/2019	19/09/2019
B32	16/08/2019	19/08/2019	23/09/2019	27/09/2019	03/10/2019	03/10/2019	07/10/2019	10/10/2019	17/10/2019
B33	13/09/2019	16/09/2019	21/10/2019	25/10/2019	31/10/2019	31/10/2019	04/11/2019	07/11/2019	14/11/2019
B34	11/10/2019	14/10/2019	18/11/2019	22/11/2019	28/11/2019	28/11/2019	02/12/2019	05/12/2019	12/12/2019
B35	29/11/2019	02/12/2019	06/01/2020	10/01/2020	16/01/2020	16/01/2020	20/01/2020	23/01/2020	30/01/2020
B36	23/12/2019	30/12/2019	03/02/2020	07/02/2020	13/02/2020	13/02/2020	17/02/2020	20/02/2020	27/02/2020
B37	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
B38	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
B39	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
B40	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
B41	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
B42									
B43	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
B44	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
B45	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
B46	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
B47	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
B48	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
B49	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

	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
B50	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
B51	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
B52	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
B53	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
B54									
B55	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
B56	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
B57	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
B58	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

(*) 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	24/01/2017	25/01/2017	08/02/2017	13/02/2017	16/02/2017	23/02/2017
C2	21/02/2017	22/02/2017	08/03/2017	13/03/2017	16/03/2017	23/03/2017
C3	22/03/2017	23/03/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
C4	18/04/2017	19/04/2017	03/05/2017	08/05/2017	11/05/2017	18/05/2017
C5	23/05/2017	24/05/2017	07/06/2017	12/06/2017	15/06/2017	22/06/2017
C6	20/06/2017	21/06/2017	05/07/2017	10/07/2017	13/07/2017	20/07/2017
C7						
C8	15/08/2017	16/08/2017	30/08/2017	04/09/2017	07/09/2017	14/09/2017
C9	12/09/2017	13/09/2017	27/09/2017	02/10/2017	05/10/2017	12/10/2017
C10	10/10/2017	11/10/2017	25/10/2017	30/10/2017	03/11/2017	09/11/2017
C11	14/11/2017	15/11/2017	29/11/2017	04/12/2017	07/12/2017	14/12/2017
C12	22/12/2017	27/12/2017	10/01/2018	15/01/2018	18/01/2018	25/01/2018
C13	23/01/2018	24/01/2018	07/02/2018	12/02/2018	15/02/2018	22/02/2018
C14	20/02/2018	21/02/2018	07/03/2018	12/03/2018	15/03/2018	22/03/2018
C15	27/03/2018	28/03/2018	11/04/2018	16/04/2018	19/04/2018	26/04/2018
C16	30/04/2018	02/05/2018	16/05/2018	22/05/2018	24/05/2018	31/05/2018
C17	29/05/2018	30/05/2018	13/06/2018	18/06/2018	21/06/2018	28/06/2018
C18	26/06/2018	27/06/2018	11/07/2018	16/07/2018	19/07/2018	26/07/2018
C19						
C20	21/08/2018	22/08/2018	05/09/2018	10/09/2018	13/09/2018	20/09/2018
C21	18/09/2018	19/09/2018	03/10/2018	08/10/2018	11/10/2018	18/10/2018
C22	16/10/2018	17/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
C23	13/11/2018	14/11/2018	28/11/2018	03/12/2018	06/12/2018	13/12/2018
C24	21/12/2018	02/01/2019	16/01/2019	21/01/2019	24/01/2019	31/01/2019
C25	29/01/2019	30/01/2019	13/02/2019	18/02/2019	21/02/2019	28/02/2019
C26	26/02/2019	27/02/2019	13/03/2019	18/03/2019	21/03/2019	28/03/2019
C27	27/03/2019	28/03/2019	10/04/2019	15/04/2019	17/04/2019	26/04/2019
C28	29/04/2019	30/04/2019	15/05/2019	20/05/2019	23/05/2019	29/05/2019
C29	28/05/2019	29/05/2019	12/06/2019	17/06/2019	20/06/2019	27/06/2019
C30	25/06/2019	26/06/2019	10/07/2019	15/07/2019	18/07/2019	25/07/2019
C32	20/08/2019	21/08/2019	04/09/2019	09/09/2019	12/09/2019	19/09/2019
C33	17/09/2019	18/09/2019	02/10/2019	07/10/2019	10/10/2019	17/10/2019
C34	15/10/2019	16/10/2019	30/10/2019	04/11/2019	07/11/2019	14/11/2019
C35	12/11/2019	13/11/2019	27/11/2019	02/12/2019	05/12/2019	12/12/2019
C36	23/12/2019	01/01/2020	15/01/2020	20/01/2020	23/01/2020	30/01/2020
C37	28/01/2020	29/01/2020	12/02/2020	17/02/2020	20/02/2020	27/02/2020
C38	25/02/2020	26/02/2020	11/03/2020	16/03/2020	19/03/2020	26/03/2020
C39	31/03/2020	01/04/2020	15/04/2020	20/04/2020	23/04/2020	30/04/2020

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	Opinion
C40	28/04/2020	29/04/2020	13/05/2020	18/05/2020	20/05/2020	28/05/2020
C41	26/05/2020	27/05/2020	10/06/2020	15/06/2020	18/06/2020	25/06/2020
C42	23/06/2020	24/06/2020	08/07/2020	13/07/2020	16/07/2020	23/07/2020
C44	18/08/2020	19/08/2020	02/09/2020	07/09/2020	10/09/2020	17/09/2020
C45	15/09/2020	16/09/2020	30/09/2020	05/10/2020	08/10/2020	15/10/2020
C46	13/10/2020	14/10/2020	28/10/2020	03/11/2020	05/11/2020	12/11/2020
C47	10/11/2020	11/11/2020	25/11/2020	30/11/2020	03/12/2020	10/12/2020
C48	23/12/2020	30/12/2020	13/01/2021	18/01/2021	21/01/2021	28/01/2021
C49	26/01/2021	27/01/2021	10/02/2021	15/02/2021	18/02/2021	25/02/2021
C50	23/02/2021	24/02/2021	10/03/2021	15/03/2021	18/03/2021	25/03/2021
C51	23/03/2021	24/03/2021	07/04/2021	12/04/2021	15/04/2021	22/04/2021
C52	20/04/2021	21/04/2021	05/05/2021	10/05/2021	12/05/2021	20/05/2021
C53	25/05/2021	26/05/2021	09/06/2021	14/06/2021	17/06/2021	24/06/2021
C54	22/06/2021	23/06/2021	07/07/2021	12/07/2021	15/07/2021	22/07/2021
C56	17/08/2021	18/08/2021	01/09/2021	06/09/2021	09/09/2021	16/09/2021
C57	14/09/2021	15/09/2021	29/09/2021	04/10/2021	07/10/2021	14/10/2021
C58	12/10/2021	13/10/2021	27/10/2021	03/11/2021	05/11/2021	11/11/2021
C59	16/11/2021	17/11/2021	01/12/2021	06/12/2021	09/12/2021	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 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[#]

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	Opinion
D1	31/01/2017	01/02/2017	08/02/2017	13/02/2017	16/02/2017	23/02/2017
D2	28/02/2017	01/03/2017	08/03/2017	13/03/2017	16/03/2017	23/03/2017
D3	29/03/2017	30/03/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
D4	25/04/2017	26/04/2017	03/05/2017	08/05/2017	11/05/2017	18/05/2017
D5	23/05/2017	31/05/2017	07/06/2017	12/06/2017	15/06/2017	22/06/2017
D6	27/06/2017	28/06/2017	05/07/2017	10/07/2017	13/07/2017	20/07/2017
D7						
D8						
D9	19/09/2017	20/09/2017	27/09/2017	02/10/2017	05/10/2017	12/10/2017
D10	17/10/2017	18/10/2017	25/10/2017	30/10/2017	03/11/2017	09/11/2017
D11	14/11/2017	22/11/2017	29/11/2017	04/12/2017	07/12/2017	14/12/2017
D12	19/12/2017	03/01/2018	10/01/2018	15/01/2018	18/01/2018	25/01/2018
D13	30/01/2018	31/01/2018	07/02/2018	12/02/2018	15/02/2018	22/02/2018
D14	27/02/2018	28/02/2018	07/03/2018	12/03/2018	15/03/2018	22/03/2018
D15	27/03/2018	04/04/2018	11/04/2018	16/04/2018	19/04/2018	26/04/2018
D16	30/04/2018	09/05/2018	16/05/2018	22/05/2018	24/05/2018	31/05/2018
D17	05/06/2018	06/06/2018	13/06/2018	18/06/2018	21/06/2018	28/06/2018
D18	03/07/2018	04/07/2018	11/07/2018	16/07/2018	19/07/2018	26/07/2018
D19						
D20						
D21	25/09/2018	26/09/2018	03/10/2018	08/10/2018	11/10/2018	18/10/2018
D22	23/10/2018	24/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
D23	20/11/2018	21/11/2018	28/11/2018	03/12/2018	06/12/2018	13/12/2018
D24	08/01/2019	09/01/2019	16/01/2019	21/01/2019	24/01/2019	31/01/2019
D25	05/02/2019	06/02/2019	13/02/2019	18/02/2019	21/02/2019	28/02/2019
D26	05/03/2019	06/03/2019	13/03/2019	18/03/2019	21/03/2019	28/03/2019
D27	03/04/2019	04/04/2019	10/04/2019	15/04/2019	17/04/2019	26/04/2019
D28	06/05/2019	07/05/2019	15/05/2019	20/05/2019	22/05/2019	29/05/2019
D29	04/06/2019	05/06/2019	12/06/2019	17/06/2019	20/06/2019	27/06/2019
D30	02/07/2019	03/07/2019	10/07/2019	15/07/2019	18/07/2019	25/07/2019
D31						
D32						
D33	24/09/2019	25/09/2019	02/10/2019	07/10/2019	10/10/2019	17/10/2019
D34	22/10/2019	23/10/2019	30/10/2019	04/11/2019	07/11/2019	14/11/2019
D35	19/11/2019	20/11/2019	27/11/2019	02/12/2019	05/12/2019	12/12/2019
D36	07/01/2020	08/01/2020	15/01/2020	20/01/2020	23/01/2020	30/01/2020
D37	04/02/2020	05/02/2020	12/02/2020	17/02/2020	20/02/2020	27/02/2020
D38	03/03/2020	04/03/2020	11/03/2020	16/03/2020	19/03/2020	26/03/2020
D39	07/04/2020	08/04/2020	15/04/2020	20/04/2020	23/04/2020	30/04/2020

	Deadline for Submission (*)	Restart	CHMP and PRAC Rapporteurs Joint AR (JAR)	Comments from PRAC and CHMP (**)	Updated CHMP and PRAC Rapporteurs JAR (~)	Opinion
D40	05/05/2020	06/05/2020	13/05/2020	18/05/2020	20/05/2020	28/05/2020
D41	02/06/2020	03/06/2020	10/06/2020	15/06/2020	18/06/2020	25/06/2020
D42	30/06/2020	01/07/2020	08/07/2020	13/07/2020	16/07/2020	23/07/2020
D43						
D44						
D45	22/09/2020	23/09/2020	30/09/2020	05/10/2020	08/10/2020	15/10/2020
D46	20/10/2020	21/10/2020	28/10/2020	03/11/2020	05/11/2020	12/11/2020
D47	17/11/2020	18/11/2020	25/11/2020	30/11/2020	03/12/2020	10/12/2020
D48	05/01/2021	06/01/2021	13/01/2021	18/01/2021	21/01/2021	28/01/2021
D49	02/02/2021	03/02/2021	10/02/2021	15/02/2021	18/02/2021	25/02/2021
D50	02/03/2021	03/03/2021	10/03/2021	15/03/2021	18/03/2021	25/03/2021
D51	30/03/2021	31/03/2021	07/04/2021	12/04/2021	15/04/2021	22/04/2021
D52	27/04/2021	28/04/2021	05/05/2021	10/05/2021	12/05/2021	20/05/2021
D53	01/06/2021	02/06/2021	09/06/2021	14/06/2021	17/06/2021	24/06/2021
D54	29/06/2021	30/06/2021	07/07/2021	12/07/2021	15/07/2021	22/07/2021
D55						
D56						
D57	21/09/2021	22/09/2021	29/09/2021	04/10/2021	07/10/2021	14/10/2021
D58	19/10/2021	20/10/2021	27/10/2021	03/11/2021	05/11/2021	11/11/2021
D59	23/11/2021	24/11/2021	01/12/2021	06/12/2021	09/12/2021	16/12/2021

(#) 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[#]

	Restart	(PRAC and) CHMP Rapporteurs Joint AR (JAR) (*)	Comments from (PRAC and) CHMP on JAR (**)	Updated (PRAC and) CHMP Rapporteurs JAR	Opinion
E1	04/01/2017	11/01/2017	16/01/2017	19/01/2017	26/01/2017
E2	01/02/2017	08/02/2017	13/02/2017	16/02/2017	23/02/2017
E3	01/03/2017	08/03/2017	13/03/2017	16/03/2017	23/03/2017
E4	30/03/2017	06/04/2017	10/04/2017	12/04/2017	21/04/2017
E5	26/04/2017	03/05/2017	08/05/2017	11/05/2017	18/05/2017
E6	31/05/2017	07/06/2017	12/06/2017	15/06/2017	22/06/2017
E7	28/06/2017	05/07/2017	10/07/2017	13/07/2017	20/07/2017
E8					
E9					
E10	20/09/2017	27/09/2017	02/10/2017	05/10/2017	12/10/2017
E11	18/10/2017	25/10/2017	30/10/2017	03/11/2017	09/11/2017
E12	22/11/2017	29/11/2017	04/12/2017	07/12/2017	14/12/2017
E13	03/01/2018	10/01/2018	15/01/2018	18/01/2018	25/01/2018
E14	31/01/2018	07/02/2018	12/02/2018	15/02/2018	22/02/2018
E15	28/02/2018	07/03/2018	12/03/2018	15/03/2018	22/03/2018
E16	04/04/2018	11/04/2018	16/04/2018	19/04/2018	26/04/2018
E17	09/05/2018	16/05/2018	22/05/2018	24/05/2018	31/05/2018
E18	06/06/2018	13/06/2018	18/06/2018	21/06/2018	28/06/2018
E19	04/07/2018	11/07/2018	16/07/2018	19/07/2018	26/07/2018
E20					
E21	26/09/2018	03/10/2018	08/10/2018	11/10/2018	18/10/2018
E22	24/10/2018	31/10/2018	05/11/2018	08/11/2018	15/11/2018
E23	21/11/2018	28/11/2018	03/12/2018	06/12/2018	13/12/2018
E24	09/01/2019	16/01/2019	21/01/2019	24/01/2019	31/01/2019
E25	06/02/2019	13/02/2019	18/02/2019	21/02/2019	28/02/2019
E26	06/03/2019	13/03/2019	18/03/2019	21/03/2019	28/03/2019
E27	04/04/2019	10/04/2019	14/04/2019	17/04/2019	26/04/2019
E28	07/05/2019	15/05/2019	20/05/2019	23/05/2019	29/05/2019
E29	05/06/2019	12/06/2019	17/06/2019	20/06/2019	27/06/2019
E30	03/07/2019	10/07/2019	15/07/2019	18/07/2019	25/07/2019
E31					
E32					
E33	25/09/2019	02/10/2019	07/10/2019	10/10/2019	17/10/2019
E34	23/10/2019	30/10/2019	04/11/2019	07/11/2019	14/11/2019
E35	20/11/2019	27/11/2019	02/12/2019	05/12/2019	12/12/2019
E36	08/01/2020	15/01/2020	20/01/2020	23/01/2020	30/01/2020
E37	05/02/2020	12/02/2020	17/02/2020	20/02/2020	27/02/2020
E38	04/03/2020	11/03/2020	16/03/2020	19/03/2020	26/03/2020

	Restart	(PRAC and) CHMP Rapporteurs Joint AR (JAR) (*)	Comments from (PRAC and) CHMP on JAR (**)	Updated (PRAC and) CHMP Rapporteurs JAR	Opinion
E39	08/04/2020	15/04/2020	20/04/2020	23/04/2020	30/04/2020
E40	06/05/2020	13/05/2020	18/05/2020	20/05/2020	28/05/2020
E41	03/06/2020	10/06/2020	15/06/2020	18/06/2020	25/06/2020
E42	01/07/2020	08/07/2020	13/07/2020	16/07/2020	23/07/2020
E43					
E44					
E45	23/09/2020	30/09/2020	05/10/2020	08/10/2020	15/10/2020
E46	21/10/2020	28/10/2020	03/11/2020	05/11/2020	12/11/2020
E47	18/11/2020	25/11/2020	30/11/2020	03/12/2020	10/12/2020
E48	06/01/2021	13/01/2021	18/01/2021	21/01/2021	28/01/2021
E49	03/02/2021	10/02/2021	15/02/2021	18/02/2021	25/02/2021
E50	03/03/2021	10/03/2021	15/03/2021	18/03/2021	25/03/2021
E51	31/03/2021	07/04/2021	12/04/2021	15/04/2021	22/04/2021
E52	28/04/2021	05/05/2021	10/05/2021	12/05/2021	20/05/2021
E53	02/06/2021	09/06/2021	14/06/2021	17/06/2021	24/06/2021
E54	30/06/2021	07/07/2021	12/07/2021	15/07/2021	22/07/2021
E55					
E56					
E57	22/09/2021	29/09/2021	04/10/2021	07/10/2021	14/10/2021
E58	20/10/2021	27/10/2021	03/11/2021	05/11/2021	11/11/2021
E59	24/11/2021	01/12/2021	06/12/2021	09/12/2021	16/12/2021

(#) 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.