



7 December 2022
EMA/3933/2022 New
Human Medicines Division

The timetables in this document may be subject to revision

Companion Diagnostic Follow-Up Consultation timetable - ATMP

30-day Initial submission assessment timetable

30-day Initial submission assessment timetable

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	CAT Rapporteur AR	PRAC outcome (~)	Comments from CAT and CHMP (**)	Updated CAT Rapporteur AR (***)	CAT Opinion	CHMP Opinion
A1	22/12/2021	29/12/2021	03/01/2022	05/01/2022	06/01/2022	11/01/2022	13/01/2022	14/01/2022	17/01/2022	21/01/2022	27/01/2022
A2	25/01/2022	26/01/2022	31/01/2022	02/02/2022	03/02/2022	08/02/2022	10/02/2022	11/02/2022	14/02/2022	18/02/2022	24/02/2022
A3	22/02/2022	23/02/2022	28/02/2022	02/03/2022	03/03/2022	08/03/2022	10/03/2022	11/03/2022	14/03/2022	18/03/2022	24/03/2022
A4	18/03/2022	21/03/2022	28/03/2022	30/03/2022	31/03/2022	05/04/2022	07/04/2022	07/04/2022	08/04/2022	13/04/2022	22/04/2022
A5	19/04/2022	20/04/2022	25/04/2022	26/04/2022	28/04/2022	03/05/2022	05/05/2022	06/05/2022	10/05/2022	13/05/2022	19/05/2022
A6	24/05/2022	25/05/2022	30/05/2022	01/06/2022	02/06/2022	07/06/2022	10/06/2022	10/06/2022	13/06/2022	17/06/2022	23/06/2022
A7	21/06/2022	22/06/2022	27/06/2022	29/06/2022	30/06/2022	05/07/2022	07/07/2022	08/07/2022	11/07/2022	15/07/2022	21/07/2022
A8											
A9	16/08/2022	17/08/2022	22/08/2022	24/08/2022	25/08/2022	30/08/2022	01/09/2022	02/09/2022	05/09/2022	09/09/2022	15/09/2022
A10	13/09/2022	14/09/2022	19/09/2022	21/09/2022	22/09/2022	27/09/2022	29/09/2022	30/09/2022	03/10/2022	07/10/2022	13/10/2022
A11	11/10/2022	12/10/2022	17/10/2022	19/10/2022	20/10/2022	25/10/2022	27/10/2022	27/10/2022	28/10/2022	04/11/2022	10/11/2022
A12	15/11/2022	16/11/2022	21/11/2022	23/11/2022	24/11/2022	29/11/2022	01/12/2022	02/12/2022	05/12/2022	09/12/2022	15/12/2022
A13	22/12/2022	28/12/2022	03/01/2023	04/01/2023	05/01/2023	10/01/2023	12/01/2023	13/01/2023	16/01/2023	20/01/2023	26/01/2023
A14	24/01/2023	25/01/2023	30/01/2023	01/02/2023	02/02/2023	07/02/2023	09/02/2023	10/02/2023	13/02/2023	17/02/2023	23/02/2023
A15	28/02/2023	01/03/2023	06/03/2023	08/03/2023	09/03/2023	14/03/2023	16/03/2023	17/03/2023	20/03/2023	24/03/2023	30/03/2023
A16	28/03/2023	29/03/2023	03/04/2023	04/04/2023	05/04/2023	11/04/2023	14/04/2023	14/04/2023	17/04/2023	21/04/2023	26/04/2023
A17	21/04/2023	24/04/2023	02/05/2023	03/05/2023	04/05/2023	10/05/2023	12/05/2023	12/05/2023	12/05/2023	17/05/2023	25/05/2023
A18	23/05/2023	24/05/2023	30/05/2023	31/05/2023	01/06/2023	06/06/2023	08/06/2023	09/06/2023	12/06/2023	16/06/2023	22/06/2023
A19	20/06/2023	21/06/2023	26/06/2023	28/06/2023	29/06/2023	04/07/2023	06/07/2023	07/07/2023	10/07/2023	14/07/2023	20/07/2023
A20											
A21	14/08/2023	16/08/2023	21/08/2023	23/08/2023	24/08/2023	29/08/2023	31/08/2023	01/09/2023	04/09/2023	08/09/2023	14/09/2023
A22	12/09/2023	13/09/2023	18/09/2023	20/09/2023	21/09/2023	26/09/2023	28/09/2023	29/09/2023	02/10/2023	06/10/2023	12/10/2023
A23	06/10/2023	08/10/2023	16/10/2023	18/10/2023	19/10/2023	24/10/2023	26/10/2023	27/10/2023	27/10/2023	31/10/2023	09/11/2023
A24	14/11/2023	15/11/2023	20/11/2023	22/11/2023	23/11/2023	28/11/2023	30/11/2023	01/12/2023	04/12/2023	08/12/2023	14/12/2023
A25	21/12/2023	27/12/2023	03/01/2024	03/01/2024	04/01/2024	09/01/2024	11/01/2024	12/01/2024	15/01/2024	19/01/2024	25/01/2024

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR (~)	Comments from PRAC (**) (~)	Updated PRAC Rapporteur AR (***) (~)	CAT Rapporteur AR	PRAC outcome (~)	Comments from CAT and CHMP (**)	Updated CAT Rapporteur AR (***)	CAT Opinion	CHMP Opinion
A26	23/01/2024	24/01/2024	29/01/2024	31/01/2024	01/02/2024	06/02/2024	08/02/2024	09/02/2024	12/02/2024	16/02/2024	22/02/2024
A27	20/02/2024	21/02/2024	26/02/2024	28/02/2024	29/02/2024	05/03/2024	07/03/2024	08/03/2024	11/03/2024	15/03/2024	21/03/2024
A28	26/03/2024	27/03/2024	02/04/2024	03/04/2024	04/04/2024	09/04/2024	11/04/2024	12/04/2024	15/04/2024	19/04/2024	25/04/2024
A29	30/04/2024	01/05/2024	06/05/2024	07/05/2024	08/05/2024	14/05/2024	16/05/2024	17/05/2024	21/05/2024	24/05/2024	30/05/2024
A30	28/05/2024	29/05/2024	03/06/2024	05/06/2024	06/06/2024	11/06/2024	13/06/2024	14/06/2024	17/06/2024	21/06/2024	27/06/2024
A31	25/06/2024	26/06/2024	01/07/2024	03/07/2024	04/07/2024	09/07/2024	11/07/2024	12/07/2024	15/07/2024	19/07/2024	25/07/2024
A32											
A33	20/08/2024	21/08/2024	26/08/2024	28/08/2024	29/08/2024	03/09/2024	05/09/2024	06/09/2024	09/09/2024	13/09/2024	19/09/2024
A34	17/09/2024	18/09/2024	23/09/2024	25/09/2024	26/09/2024	01/10/2024	03/10/2024	04/10/2024	07/10/2024	11/10/2024	17/10/2024
A35	15/10/2024	16/10/2024	21/10/2024	23/10/2024	24/10/2024	29/10/2024	31/10/2024	31/10/2024	04/11/2024	08/11/2024	14/11/2024
A36	12/11/2024	13/11/2024	18/11/2024	20/11/2024	21/11/2024	26/11/2024	28/11/2024	29/11/2024	02/12/2024	06/12/2024	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 submission, in which case the submission is considered void and it needs to be re-despatched.

(**) Comments from CAT, 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, CAT) members which create the need for the update.

(~) Step applicable only in case of PRAC involvement.