

31 October 2017
EMA/251635/2015 Rev.2
Human Medicines Evaluation

The timetables in this document may be subject to revision

Periodic Safety Update Report (PSUR)/PSUR Single Assessment (PSUSA) - ATMPs

	Start date (*)	PRAC Rapporteur AR	Comments from PRAC/MAH (**)	Updated PRAC Rapporteur AR (***)	PRAC Recommendation	CAT/CHMP members comments (**)	CAT Opinion	CHMP Opinion
A1	10/02/2017	11/04/2017	11/05/2017	29/05/2017	09/06/2017	14/06/2017	16/06/2017	22/06/2017
A2	09/03/2017	08/05/2017	07/06/2017	22/06/2017	06/07/2017	11/07/2017	14/07/2017	20/07/2017
A3								
A4	05/05/2017	04/07/2017	03/08/2017	18/08/2017	01/09/2017	06/09/2017	08/09/2017	14/09/2017
A5	01/06/2017	31/07/2017	30/08/2017	14/09/2017	28/09/2017	03/10/2017	06/10/2017	12/10/2017
A6	29/06/2017	29/08/2017	27/09/2017	12/10/2017	26/10/2017	30/10/2017	31/10/2017	09/11/2017
A7	03/08/2017	02/10/2017	03/11/2017	16/11/2017	30/11/2017	05/12/2017	08/12/2017	14/12/2017
A8	14/09/2017	13/11/2017	13/12/2017	28/12/2017	11/01/2018	17/01/2018	19/01/2018	25/01/2018
A9	12/10/2017	11/12/2017	10/01/2018	25/01/2018	08/02/2018	13/02/2018	16/02/2018	22/02/2018
A10	09/11/2017	08/01/2018	07/02/2018	22/02/2018	08/03/2018	13/03/2018	16/03/2018	22/03/2018
A11	14/12/2017	12/02/2018	14/03/2018	03/04/2018	12/04/2018	17/04/2018	20/04/2018	26/04/2018
A12	18/01/2018	19/03/2018	18/04/2018	03/05/2018	17/05/2018	23/05/2018	25/05/2018	31/05/2018
A13	15/02/2018	16/04/2018	16/05/2018	31/05/2018	14/06/2018	19/06/2018	22/06/2018	28/06/2018
A14	15/03/2018	14/05/2018	13/06/2018	28/06/2018	12/07/2018	17/07/2018	20/07/2018	26/07/2018
A15								
A16	10/05/2018	09/07/2018	08/08/2018	23/08/2018	06/09/2018	11/09/2018	14/09/2018	20/09/2018

	Start date (*)	PRAC Rapporteur AR	Comments from PRAC/MAH (**)	Updated PRAC Rapporteur AR (***)	PRAC Recommendation	CAT/CHMP members comments (**)	CAT Opinion	CHMP Opinion
A17	07/06/2018	06/08/2018	05/09/2018	20/09/2018	04/10/2018	09/10/2018	12/10/2018	18/10/2018
A18	04/07/2018	03/09/2018	02/10/2018	17/10/2018	31/10/2018	06/11/2018	09/11/2018	15/11/2018
A19	02/08/2018	01/10/2018	31/10/2018	15/11/2018	29/11/2018	04/12/2018	07/12/2018	13/12/2018
A20	20/09/2018	19/11/2018	19/12/2018	03/01/2019	17/01/2019	22/01/2019	25/01/2019	31/01/2019
A21	18/10/2018	17/12/2018	16/01/2019	31/01/2019	14/02/2019	19/02/2019	22/02/2019	28/02/2019
A22	15/11/2018	14/01/2019	13/02/2019	28/02/2019	14/03/2019	19/03/2019	22/03/2019	28/03/2019
A23	13/12/2018	11/02/2019	13/03/2019	28/03/2019	11/04/2019	12/03/2019	17/04/2019	26/04/2019
A24	17/01/2019	18/03/2019	17/04/2019	02/05/2019	16/05/2019	21/05/2019	24/05/2019	29/05/2019
A25	15/02/2019	16/04/2019	16/05/2019	30/05/2019	14/06/2019	18/06/2019	21/06/2019	27/06/2019
A26	14/03/2019	13/05/2019	12/06/2019	27/06/2019	11/07/2019	16/07/2019	19/07/2019	25/07/2019
A27								
A28	09/05/2019	08/07/2019	07/08/2019	22/08/2019	05/09/2019	10/09/2019	13/09/2019	19/09/2019
A29	06/06/2019	05/08/2019	04/09/2019	19/09/2019	03/10/2019	08/10/2019	11/10/2019	17/10/2019
A30	04/07/2019	02/09/2019	02/10/2019	17/10/2019	31/10/2019	05/11/2019	08/11/2019	14/11/2019
A31	01/08/2019	30/09/2019	30/10/2019	14/11/2019	28/11/2019	03/12/2019	06/12/2019	12/12/2019
A32	19/09/2019	18/11/2019	18/12/2019	02/01/2020	16/01/2020	21/01/2020	24/01/2020	30/01/2020
A33	17/10/2019	16/12/2019	15/01/2020	30/01/2020	13/02/2020	18/02/2020	21/02/2020	27/02/2020
A34	14/11/2019	13/01/2020	12/02/2020	27/02/2020	12/03/2020	17/03/2020	20/03/2020	26/03/2020
A35	20/12/2019	18/02/2020	19/03/2020	03/04/2020	17/04/2020	21/04/2020	24/04/2020	30/04/2020
A36	16/01/2020	16/03/2020	15/04/2020	30/04/2020	14/05/2020	15/05/2020	20/05/2020	28/05/2020
A37	13/02/2020	14/04/2020	13/05/2020	28/05/2020	11/06/2020	16/06/2020	19/06/2020	25/06/2020
A38	12/03/2020	11/05/2020	10/06/2020	25/06/2020	09/07/2020	14/07/2020	17/07/2020	23/07/2020
A39								
A40	08/05/2020	07/07/2020	06/08/2020	21/08/2020	04/09/2020	08/09/2020	11/09/2020	17/09/2020
A41	04/06/2020	03/08/2020	02/09/2020	17/09/2020	01/10/2020	06/10/2020	09/10/2020	15/10/2020
A42	02/07/2020	01/09/2020	30/09/2020	15/10/2020	29/10/2020	03/11/2020	06/11/2020	12/11/2020

	Start date (*)	PRAC Rapporteur AR	Comments from PRAC/MAH (**)	Updated PRAC Rapporteur AR (***)	PRAC Recommendation	CAT/CHMP members comments (**)	CAT Opinion	CHMP Opinion
A43	30/07/2020	28/09/2020	28/10/2020	12/11/2020	26/11/2020	01/12/2020	04/12/2020	10/12/2020
A44	17/09/2020	16/11/2020	16/12/2020	31/12/2020	14/01/2021	19/01/2021	22/01/2021	28/01/2021
A45	15/10/2020	14/12/2020	13/01/2021	28/01/2021	11/02/2021	16/02/2021	19/02/2021	25/02/2021
A46	12/11/2020	11/01/2021	10/02/2021	25/02/2021	11/03/2021	16/03/2021	19/03/2021	25/03/2021
A47	11/12/2020	09/02/2021	11/03/2021	26/03/2021	09/04/2021	13/04/2021	16/04/2021	22/04/2021
A48	07/01/2021	08/03/2021	07/04/2021	22/04/2021	06/05/2021	07/05/2021	12/05/2021	20/05/2021
A49	11/02/2021	12/04/2021	12/05/2021	27/05/2021	10/06/2021	15/06/2021	18/06/2021	24/06/2021
A50	11/03/2021	10/05/2021	09/06/2021	24/06/2021	08/07/2021	13/07/2021	16/07/2021	22/07/2021
A51								
A52	07/05/2021	06/07/2021	05/08/2021	20/08/2021	03/09/2021	07/09/2021	10/09/2021	16/09/2021
A53	03/06/2021	02/08/2021	01/09/2021	16/09/2021	30/09/2021	05/10/2021	08/10/2021	14/10/2021
A54	01/07/2021	31/08/2021	29/09/2021	14/10/2021	28/10/2021	02/11/2021	05/11/2021	11/11/2021
A55	05/08/2021	04/10/2021	03/11/2021	18/11/2021	02/12/2021	07/12/2021	10/12/2021	16/12/2021

(*) As there is no submission cut-off date, any ATMP PSUR submitted until the day before procedure start will be started on the procedure start date.

(**) Comments from PRAC, CAT or CHMP members are not made available to Marketing Authorisation Holders (MAHs).

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