



29 November 2019  
EMA/251636/2015 Rev.5  
Human Medicines Evaluation

The timetables in this document may be subject to revision

## Periodic Safety Update Report (PSUR)/PSUR Single Assessment (PSUSA)

	PSUR/PSUSA cut off date(*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH (**)	Updated PRAC Rapporteur AR (***)	PRAC Recommendation	CHMP/CMD(h) members comments (**)(~)	CHMP Opinion/CMD(h) position
A1	25/01/2017	10/02/2017	11/04/2017	11/05/2017	29/05/2017	09/06/2017	15/06/2017	22/06/2017
A2	21/02/2017	09/03/2017	08/05/2017	07/06/2017	22/06/2017	06/07/2017	13/07/2017	20/07/2017
A3								
A4	19/04/2017	05/05/2017	04/07/2017	03/08/2017	18/08/2017	01/09/2017	07/09/2017	14/09/2017
A5	16/05/2017	01/06/2017	31/07/2017	30/08/2017	14/09/2017	28/09/2017	05/10/2017	12/10/2017
A6	13/06/2017	29/06/2017	29/08/2017	27/09/2017	12/10/2017	26/10/2017	03/11/2017	09/11/2017
A7	18/07/2017	03/08/2017	02/10/2017	03/11/2017	16/11/2017	30/11/2017	07/12/2017	14/12/2017
A8	29/08/2017	14/09/2017	13/11/2017	13/12/2017	28/12/2017	11/01/2018	18/01/2018	25/01/2018
A9	26/09/2017	12/10/2017	11/12/2017	10/01/2018	25/01/2018	08/02/2018	15/02/2018	22/02/2018
A10	24/10/2017	09/11/2017	08/01/2018	07/02/2018	22/02/2018	08/03/2018	15/03/2018	22/03/2018
A11	28/11/2017	14/12/2017	12/02/2018	14/03/2018	03/04/2018	12/04/2018	19/04/2018	26/04/2018
A12	03/01/2018	18/01/2018	19/03/2018	18/04/2018	03/05/2018	17/05/2018	24/05/2018	31/05/2018
A13	30/01/2018	15/02/2018	16/04/2018	16/05/2018	31/05/2018	14/06/2018	21/06/2018	28/06/2018
A14	27/02/2018	15/03/2018	14/05/2018	13/06/2018	28/06/2018	12/07/2018	19/07/2018	26/07/2018
A15								
A16	23/04/2018	10/05/2018	09/07/2018	08/08/2018	23/08/2018	06/09/2018	13/09/2018	20/09/2018

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

	PSUR/PSUSA cut off date(*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH (**)	Updated PRAC Rapporteur AR (***)	PRAC Recommendation	CHMP/CMD(h) members comments (**) (~)	CHMP Opinion/CMD(h) position
A43	23/07/2020	30/07/2020	28/09/2020	28/10/2020	12/11/2020	26/11/2020	03/12/2020	10/12/2020
A44	10/09/2020	17/09/2020	16/11/2020	16/12/2020	31/12/2020	14/01/2021	21/01/2021	28/01/2021
A45	08/10/2020	15/10/2020	14/12/2020	13/01/2021	28/01/2021	11/02/2021	18/02/2021	25/02/2021
A46	05/11/2020	12/11/2020	11/01/2021	10/02/2021	25/02/2021	11/03/2021	18/03/2021	25/03/2021
A47	04/12/2020	11/12/2020	09/02/2021	11/03/2021	26/03/2021	09/04/2021	15/04/2021	22/04/2021
A48	22/12/2020	07/01/2021	08/03/2021	07/04/2021	22/04/2021	06/05/2021	12/05/2021	20/05/2021
A49	04/02/2021	11/02/2021	12/04/2021	12/05/2021	27/05/2021	10/06/2021	17/06/2021	24/06/2021
A50	10/03/2021	11/03/2021	10/05/2021	09/06/2021	24/06/2021	08/07/2021	15/07/2021	22/07/2021
A51								
A52	22/04/2021	07/05/2021	06/07/2021	05/08/2021	20/08/2021	03/09/2021	09/09/2021	16/09/2021
A53	27/05/2021	03/06/2021	02/08/2021	01/09/2021	16/09/2021	30/09/2021	07/10/2021	14/10/2021
A54	24/06/2021	01/07/2021	31/08/2021	29/09/2021	14/10/2021	28/10/2021	04/11/2021	11/11/2021
A55	29/07/2021	05/08/2021	04/10/2021	03/11/2021	18/11/2021	02/12/2021	09/12/2021	16/12/2021

(\*) The period between PSUR/PSUSA cut-off date and start date is established to allow Marketing Authorisation Holders (MAHs) resolution of any technical issues ahead of the planned procedure start, as well as administrative processing of starting PSUR/PSUSAs by the Agency. In order to manage the missing April start date, the cut-off periods for March and May starts are adapted.

The Agency strongly recommends submitting the application before the legally binding submission deadline as stated in the List of Union reference dates (EURD list). 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 PRAC, CHMP or CMDh 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.