



15 March 2021
EMA/251636/2015 Rev.8
Human Medicines Division



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	09/01/2020	16/01/2020	16/03/2020	15/04/2020	30/04/2020	14/05/2020	20/05/2020	28/05/2020
A2	06/02/2020	13/02/2020	14/04/2020	13/05/2020	28/05/2020	11/06/2020	18/06/2020	25/06/2020
A3	11/03/2020	12/03/2020	11/05/2020	10/06/2020	25/06/2020	09/07/2020	16/07/2020	23/07/2020
A4								
A5	23/04/2020	08/05/2020	07/07/2020	06/08/2020	21/08/2020	04/09/2020	10/09/2020	17/09/2020
A6	28/05/2020	04/06/2020	03/08/2020	02/09/2020	17/09/2020	01/10/2020	08/10/2020	15/10/2020
A7	25/06/2020	02/07/2020	01/09/2020	30/09/2020	15/10/2020	29/10/2020	05/11/2020	12/11/2020
A8	23/07/2020	30/07/2020	28/09/2020	28/10/2020	12/11/2020	26/11/2020	03/12/2020	10/12/2020
A9	10/09/2020	17/09/2020	16/11/2020	16/12/2020	31/12/2020	14/01/2021	21/01/2021	28/01/2021
A10	08/10/2020	15/10/2020	14/12/2020	13/01/2021	28/01/2021	11/02/2021	18/02/2021	25/02/2021
A11	05/11/2020	12/11/2020	11/01/2021	10/02/2021	25/02/2021	11/03/2021	18/03/2021	25/03/2021
A12	04/12/2020	11/12/2020	09/02/2021	11/03/2021	26/03/2021	09/04/2021	15/04/2021	22/04/2021
A13	22/12/2020	07/01/2021	08/03/2021	07/04/2021	22/04/2021	06/05/2021	12/05/2021	20/05/2021
A14	04/02/2021	11/02/2021	12/04/2021	12/05/2021	27/05/2021	10/06/2021	17/06/2021	24/06/2021
A15	10/03/2021	11/03/2021	10/05/2021	09/06/2021	24/06/2021	08/07/2021	15/07/2021	22/07/2021
A16								
A17	22/04/2021	07/05/2021	06/07/2021	05/08/2021	20/08/2021	02/09/2021	09/09/2021	16/09/2021

	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
A18	27/05/2021	03/06/2021	02/08/2021	01/09/2021	16/09/2021	30/09/2021	07/10/2021	14/10/2021
A19	24/06/2021	01/07/2021	31/08/2021	29/09/2021	14/10/2021	28/10/2021	04/11/2021	11/11/2021
A20	29/07/2021	05/08/2021	04/10/2021	03/11/2021	18/11/2021	02/12/2021	09/12/2021	16/12/2021
A21	09/09/2021	16/09/2021	15/11/2021	15/12/2021	30/12/2021	13/01/2022	20/01/2022	27/01/2022
A22	07/10/2021	14/10/2021	13/12/2021	12/01/2022	27/01/2022	10/02/2022	17/02/2022	24/02/2022
A23	04/11/2021	11/11/2021	10/01/2022	09/02/2022	24/02/2022	10/03/2022	17/03/2022	24/03/2022
A24	02/12/2021	09/12/2021	07/02/2022	09/03/2022	24/03/2022	07/04/2022	13/04/2022	22/04/2022
A25	22/12/2021	06/01/2022	07/03/2022	06/04/2022	21/04/2022	05/05/2022	12/05/2022	19/05/2022
A26	04/02/2022	11/02/2022	12/04/2022	12/05/2022	27/05/2022	10/06/2022	16/06/2022	23/06/2022
A27	09/03/2022	10/03/2022	09/05/2022	08/06/2022	23/06/2022	07/07/2022	14/07/2022	21/07/2022
A28								
A29	21/04/2022	05/05/2022	04/07/2022	03/08/2022	18/08/2022	01/09/2022	08/09/2022	15/09/2022
A30	25/05/2022	02/06/2022	01/08/2022	31/08/2022	15/09/2022	29/09/2022	06/10/2022	13/10/2022
A31	23/06/2022	30/06/2022	29/08/2022	28/09/2022	13/10/2022	27/10/2022	03/11/2022	10/11/2022
A32	28/07/2022	04/08/2022	03/10/2022	02/11/2022	17/11/2022	01/12/2022	08/12/2022	15/12/2022
A33	08/09/2022	15/09/2022	14/11/2022	14/12/2022	29/12/2022	12/01/2023	19/01/2023	26/01/2023
A34	06/10/2022	13/10/2022	12/12/2022	11/01/2023	26/01/2023	09/02/2023	16/02/2023	23/02/2023
A35	10/11/2022	17/11/2022	16/01/2023	15/02/2023	02/03/2023	16/03/2023	23/03/2023	30/03/2023
A36	09/12/2022	16/12/2022	14/02/2023	16/03/2023	31/03/2023	14/04/2023	19/04/2023	26/04/2023
A37	06/01/2023	13/01/2023	14/03/2023	13/04/2023	28/04/2023	12/05/2023	17/05/2023	25/05/2023
A38	02/02/2023	09/02/2023	10/04/2023	10/05/2023	25/05/2023	08/06/2023	15/06/2023	22/06/2023
A39	08/03/2023	09/03/2023	08/05/2023	07/06/2023	22/06/2023	06/07/2023	13/07/2023	20/07/2023
A40								
A41	20/04/2023	04/05/2023	03/07/2023	02/08/2023	17/08/2023	31/08/2023	07/09/2023	14/09/2023
A42	25/05/2023	01/06/2023	31/07/2023	30/08/2023	14/09/2023	28/09/2023	05/10/2023	12/10/2023
A43	22/06/2023	29/06/2023	28/08/2023	27/09/2023	12/10/2023	26/10/2023	31/10/2023	09/11/2023
A44	27/07/2023	03/08/2023	02/10/2023	01/11/2023	16/11/2023	30/11/2023	07/12/2023	14/12/2023

	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
A45	07/09/2023	14/09/2023	13/11/2023	13/12/2023	28/12/2023	11/01/2024	18/01/2024	25/01/2024
A46	05/10/2023	12/10/2023	11/12/2023	10/01/2024	25/01/2024	08/02/2024	15/02/2024	22/02/2024
A47	31/10/2023	09/11/2023	08/01/2024	07/02/2024	22/02/2024	07/03/2024	14/03/2024	21/03/2024
A48	07/12/2023	14/12/2023	12/02/2024	13/03/2024	28/03/2024	11/04/2024	18/04/2024	25/04/2024
A49	11/01/2024	18/01/2024	18/03/2024	17/04/2024	02/05/2024	16/05/2024	23/05/2024	30/05/2024
A50	08/02/2024	15/02/2024	15/04/2024	15/05/2024	30/05/2024	13/06/2024	20/06/2024	27/06/2024
A51	13/03/2024	14/03/2024	13/05/2024	12/06/2024	27/06/2024	11/07/2024	18/07/2024	25/07/2024
A52								
A53	25/04/2024	09/05/2024	08/07/2024	07/08/2024	22/08/2024	05/09/2024	12/09/2024	19/09/2024
A54	30/05/2024	06/06/2024	05/08/2024	04/09/2024	19/09/2024	03/10/2024	10/10/2024	17/10/2024
A55	27/06/2024	04/07/2024	02/09/2024	02/10/2024	17/10/2024	31/10/2024	07/11/2024	14/11/2024
A56	25/07/2024	01/08/2024	30/09/2024	30/10/2024	14/11/2024	28/11/2024	05/12/2024	12/12/2024

(*) 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.