



6 July 2018
EMA/267915/2016 Rev.1
Human Medicines Evaluation

The timetables in this document may be subject to revision

Safety Signal - Assessment of responses to Request for Supplementary Information (RSI) - ATMP

[30-day](#)

[60-day](#)

[90-day](#)

30-day assessment timetable⁷

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CAT adoption	CHMP adoption (^)
A1	08/06/2018	13/06/2018	27/06/2018	02/07/2018	05/07/2018	12/07/2018	20/07/2018	26/07/2018
A2								
A3	03/08/2018	08/08/2018	22/08/2018	28/08/2018	30/08/2018	06/09/2018	14/09/2018	20/09/2018
A4	31/08/2018	05/09/2018	19/09/2018	24/09/2018	27/09/2018	04/10/2018	12/10/2018	18/10/2018
A5	28/09/2018	03/10/2018	17/10/2018	22/10/2018	25/10/2018	31/10/2018	09/11/2018	15/11/2018
A6	26/10/2018	31/10/2018	14/11/2018	19/11/2018	22/11/2018	29/11/2018	07/12/2018	13/12/2018
A7	07/12/2018	19/12/2018	03/01/2019	07/01/2019	10/01/2019	17/01/2019	25/01/2019	31/01/2019
A8	11/01/2019	16/01/2019	30/01/2019	04/02/2019	07/02/2019	14/02/2019	22/02/2019	28/02/2019
A9	08/02/2019	13/02/2019	27/02/2019	04/03/2019	07/03/2019	14/03/2019	22/03/2019	28/03/2019
A10	08/03/2019	13/03/2019	27/03/2019	01/04/2019	04/04/2019	11/04/2019	17/04/2019	26/04/2019
A11	05/04/2019	17/04/2019	26/04/2019	03/05/2019	07/05/2019	16/05/2019	24/05/2019	29/05/2019
A12	06/05/2019	16/05/2019	24/05/2019	29/05/2019	04/06/2019	14/06/2019	21/06/2019	27/06/2019
A13	07/06/2019	12/06/2019	26/06/2019	01/07/2019	04/07/2019	11/07/2019	19/07/2019	25/07/2019
A14								
A15	02/08/2019	07/08/2019	21/08/2019	27/08/2019	29/08/2019	05/09/2019	13/09/2019	19/09/2019
A16	30/08/2019	04/09/2019	18/09/2019	23/09/2019	26/09/2019	03/10/2019	11/10/2019	17/10/2019
A17	27/09/2019	02/10/2019	16/10/2019	21/10/2019	24/10/2019	31/10/2019	08/11/2019	14/11/2019
A18	25/10/2019	30/10/2019	13/11/2019	18/11/2019	21/11/2019	28/11/2019	06/12/2019	12/12/2019
A19	06/12/2019	18/12/2019	03/01/2020	07/01/2020	09/01/2020	16/01/2020	24/01/2020	30/01/2020
A20	10/01/2020	15/01/2020	29/01/2020	03/02/2020	06/02/2020	13/02/2020	21/02/2020	27/02/2020
A21	07/02/2020	12/02/2020	26/02/2020	02/03/2020	05/03/2020	12/03/2020	20/03/2020	26/03/2020
A22	16/03/2020	19/03/2020	01/04/2020	06/04/2020	08/04/2020	17/04/2020	24/04/2020	30/04/2020
A23	08/04/2020	15/04/2020	29/04/2020	04/05/2020	07/05/2020	14/05/2020	20/05/2020	28/05/2020
A24	08/05/2020	13/05/2020	27/05/2020	02/06/2020	04/06/2020	11/06/2020	19/06/2020	25/06/2020
A25	05/06/2020	10/06/2020	24/06/2020	29/06/2020	02/07/2020	09/07/2020	17/07/2020	23/07/2020
A26								
A27	03/08/2020	06/08/2020	19/08/2020	24/08/2020	27/08/2020	04/09/2020	11/09/2020	17/09/2020
A28	28/08/2020	02/09/2020	16/09/2020	21/09/2020	24/09/2020	01/10/2020	09/10/2020	15/10/2020
A29	25/09/2020	30/09/2020	14/10/2020	19/10/2020	22/10/2020	29/10/2020	06/11/2020	12/11/2020
A30	23/10/2020	28/10/2020	11/11/2020	16/11/2020	19/11/2020	26/11/2020	04/12/2020	10/12/2020
A31	04/12/2020	16/12/2020	04/01/2021	06/01/2021	07/01/2021	14/01/2021	22/01/2021	28/01/2021
A32	08/01/2021	13/01/2021	27/01/2021	01/02/2021	04/02/2021	11/02/2021	19/02/2021	25/02/2021
A33	05/02/2021	10/02/2021	24/02/2021	01/03/2021	04/03/2021	11/03/2021	19/03/2021	25/03/2021
A34	08/03/2021	11/03/2021	24/03/2021	29/03/2021	31/03/2021	09/04/2021	16/04/2021	22/04/2021
A35	30/03/2021	07/04/2021	21/04/2021	26/04/2021	29/04/2021	06/05/2021	12/05/2021	20/05/2021
A36	07/05/2021	12/05/2021	26/05/2021	31/05/2021	03/06/2021	10/06/2021	18/06/2021	24/06/2021
A37	04/06/2021	09/06/2021	23/06/2021	28/06/2021	01/07/2021	08/07/2021	16/07/2021	22/07/2021
A38								
A39	02/08/2021	05/08/2021	18/08/2021	23/08/2021	26/08/2021	03/09/2021	10/09/2021	16/09/2021
A40	27/08/2021	01/09/2021	15/09/2021	20/09/2021	23/09/2021	30/09/2021	08/10/2021	14/10/2021
A41	24/09/2021	29/09/2021	13/10/2021	18/10/2021	21/10/2021	28/10/2021	05/11/2021	11/11/2021
A42	27/10/2021	03/11/2021	17/11/2021	22/11/2021	25/11/2021	02/12/2021	10/12/2021	16/12/2021

(-) The applicability of a 90-, 60- or 30-day timetable will be specified at the time of the preceding RSI.

(*) 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.

(#) An updated AR is optional and dependent on the comments received from PRAC members and Marketing Authorisation Holders (MAHs) which create the need for the update.

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of centrally authorised products.

60-day assessment timetable⁷

	Deadline for Submission (*)	Start date	PRAC Rapporteur AR	Comments from PRAC/MAH	Updated PRAC Rapporteur AR (#)	PRAC conclusion	CAT adoption	CHMP adoption (^)
B1	08/05/2018	14/05/2018	18/06/2018	02/07/2018	05/07/2018	12/07/2018	20/07/2018	26/07/2018
B2								
B3	04/07/2018	09/07/2018	13/08/2018	28/08/2018	30/08/2018	06/09/2018	14/09/2018	20/09/2018
B4	01/08/2018	06/08/2018	10/09/2018	24/09/2018	27/09/2018	04/10/2018	12/10/2018	18/10/2018
B5	29/08/2018	03/09/2018	08/10/2018	22/10/2018	25/10/2018	31/10/2018	09/11/2018	15/11/2018
B6	26/09/2018	01/10/2018	05/11/2018	19/11/2018	22/11/2018	29/11/2018	07/12/2018	13/12/2018
B7	07/11/2018	19/11/2018	14/12/2018	07/01/2019	10/01/2019	17/01/2019	25/01/2019	31/01/2019
B8	12/12/2018	17/12/2018	21/01/2019	04/02/2019	07/02/2019	14/02/2019	22/02/2019	28/02/2019
B9	09/01/2019	14/01/2019	18/02/2019	04/03/2019	07/03/2019	14/03/2019	22/03/2019	28/03/2019
B10	06/02/2019	11/02/2019	18/03/2019	01/04/2019	04/04/2019	11/04/2019	17/04/2019	26/04/2019
B11	06/03/2019	18/03/2019	16/04/2019	29/04/2019	06/05/2019	16/05/2019	24/05/2019	29/05/2019
B12	11/04/2019	16/04/2019	20/05/2019	03/06/2019	06/06/2019	14/06/2019	21/06/2019	27/06/2019
B13	07/05/2019	13/05/2019	17/06/2019	01/07/2019	04/07/2019	11/07/2019	19/07/2019	25/07/2019
B14								
B15	03/07/2019	08/07/2019	12/08/2019	27/08/2019	29/08/2019	05/09/2019	13/09/2019	19/09/2019
B16	31/07/2019	05/08/2019	09/09/2019	23/09/2019	26/09/2019	03/10/2019	11/10/2019	17/10/2019
B17	28/08/2019	02/09/2019	07/10/2019	21/10/2019	24/10/2019	31/10/2019	08/11/2019	14/11/2019
B18	25/09/2019	30/09/2019	04/11/2019	18/11/2019	21/11/2019	28/11/2019	06/12/2019	12/12/2019
B19	06/11/2019	18/11/2019	13/12/2019	06/01/2020	09/01/2020	16/01/2020	24/01/2020	30/01/2020
B20	11/12/2019	16/12/2019	20/01/2020	03/02/2020	06/02/2020	13/02/2020	21/02/2020	27/02/2020
B21	08/01/2020	13/01/2020	17/02/2020	02/03/2020	05/03/2020	12/03/2020	20/03/2020	26/03/2020
B22	10/02/2020	18/02/2020	20/03/2020	03/04/2020	06/04/2020	17/04/2020	24/04/2020	30/04/2020
B23	11/03/2020	16/03/2020	20/04/2020	04/05/2020	07/05/2020	14/05/2020	20/05/2020	28/05/2020
B24	06/04/2020	13/04/2020	18/05/2020	28/05/2020	04/06/2020	11/06/2020	19/06/2020	25/06/2020
B25	06/05/2020	11/05/2020	15/06/2020	29/06/2020	02/07/2020	09/07/2020	17/07/2020	23/07/2020
B26								
B27	02/07/2020	07/07/2020	10/08/2020	24/08/2020	27/08/2020	04/09/2020	11/09/2020	17/09/2020
B28	29/07/2020	03/08/2020	07/09/2020	21/09/2020	24/09/2020	01/10/2020	09/10/2020	15/10/2020
B29	26/08/2020	31/08/2020	05/10/2020	19/10/2020	22/10/2020	29/10/2020	06/11/2020	12/11/2020
B30	23/09/2020	28/09/2020	04/11/2020	16/11/2020	19/11/2020	26/11/2020	04/12/2020	10/12/2020
B31	11/11/2020	16/11/2020	21/12/2020	04/01/2021	07/01/2021	14/01/2021	22/01/2021	28/01/2021
B32	09/12/2020	14/12/2020	18/01/2021	01/02/2021	04/02/2021	11/02/2021	19/02/2021	25/02/2021
B33	06/01/2021	11/01/2021	15/02/2021	01/03/2021	04/03/2021	11/03/2021	19/03/2021	25/03/2021
B34	04/02/2021	09/02/2021	15/03/2021	29/03/2021	31/03/2021	09/04/2021	16/04/2021	22/04/2021
B35	03/03/2021	08/03/2021	12/04/2021	26/04/2021	29/04/2021	06/05/2021	12/05/2021	20/05/2021
B36	07/04/2021	12/04/2021	17/05/2021	31/05/2021	03/06/2021	10/06/2021	18/06/2021	24/06/2021
B37	05/05/2021	10/05/2021	14/06/2021	28/06/2021	01/07/2021	08/07/2021	16/07/2021	22/07/2021
B38								
B39	01/07/2021	06/07/2021	09/08/2021	23/08/2021	26/08/2021	03/09/2021	10/09/2021	16/09/2021
B40	28/07/2021	02/08/2021	06/09/2021	20/09/2021	23/09/2021	30/09/2021	08/10/2021	14/10/2021
B41	25/08/2021	30/08/2021	04/10/2021	18/10/2021	21/10/2021	28/10/2021	05/11/2021	11/11/2021
B42	29/09/2021	04/10/2021	08/11/2021	22/11/2021	25/11/2021	02/12/2021	10/12/2021	16/12/2021

(-) The applicability of a 90-, 60- or 30-day timetable will be specified at the time of the preceding RSI.

(*) 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.

(#) An updated AR is optional and dependent on the comments received from PRAC members and Marketing Authorisation Holders (MAHs) which create the need for the update.

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of centrally authorised products.

90-day assessment timetable ⁷

	Deadline for Submission (*)	Start date	Individual PRAC Rapporteurs/ Lead MSs AR (-)	Preliminary PRAC Rapporteur Joint AR	Comments from PRAC/MAH	Updated PRAC Rapporteur Joint AR (#)	PRAC conclusion	CAT adoption	CHMP adoption (^)
C1	11/04/2018	14/04/2018	14/05/2018	12/06/2018	27/06/2018	05/07/2018	12/07/2018	20/07/2018	26/07/2018
C2									
C3	06/06/2018	09/06/2018	09/07/2018	07/08/2018	22/08/2018	30/08/2018	06/09/2018	14/09/2018	20/09/2018
C4	04/07/2018	07/07/2018	06/08/2018	04/09/2018	19/09/2018	27/09/2018	04/10/2018	12/10/2018	18/10/2018
C5	31/07/2018	03/08/2018	03/09/2018	01/10/2018	16/10/2018	24/10/2018	31/10/2018	09/11/2018	15/11/2018
C6	29/08/2018	01/09/2018	01/10/2018	30/10/2018	14/11/2018	22/11/2018	29/11/2018	07/12/2018	13/12/2018
C7	08/10/2018	20/10/2018	12/11/2018	11/12/2018	03/01/2019	10/01/2019	17/01/2019	25/01/2019	31/01/2019
C8	14/11/2018	17/11/2018	17/12/2018	15/01/2019	30/01/2019	07/02/2019	14/02/2019	22/02/2019	28/02/2019
C9	12/12/2018	15/12/2018	14/01/2019	12/02/2019	27/02/2019	07/03/2019	14/03/2019	22/03/2019	28/03/2019
C10	09/01/2019	12/01/2019	11/02/2019	12/03/2019	27/03/2019	04/04/2019	11/04/2019	17/04/2019	26/04/2019
C11	13/02/2019	16/02/2019	15/03/2019	15/04/2019	30/04/2019	08/05/2019	16/05/2019	24/05/2019	29/05/2019
C12	12/03/2019	17/03/2019	15/04/2019	14/05/2019	28/05/2019	06/06/2019	14/06/2019	21/06/2019	27/06/2019
C13	10/04/2019	13/04/2019	13/05/2019	11/06/2019	26/06/2019	04/07/2019	11/07/2019	19/07/2019	25/07/2019
C14									
C15	05/06/2019	08/06/2019	08/07/2019	06/08/2019	21/08/2019	29/08/2019	05/09/2019	13/09/2019	19/09/2019
C16	03/07/2019	06/07/2019	05/08/2019	03/09/2019	18/09/2019	26/09/2019	03/10/2019	11/10/2019	17/10/2019
C17	31/07/2019	03/08/2019	02/09/2019	01/10/2019	16/10/2019	24/10/2019	31/10/2019	08/11/2019	14/11/2019
C18	28/08/2019	31/08/2019	30/09/2019	29/10/2019	13/11/2019	21/11/2019	28/11/2019	06/12/2019	12/12/2019
C19	09/10/2019	19/10/2019	11/11/2019	11/12/2019	03/01/2020	09/01/2020	16/01/2020	24/01/2020	30/01/2020
C20	13/11/2019	16/11/2019	16/12/2019	14/01/2020	29/01/2020	06/02/2020	13/02/2020	21/02/2020	27/02/2020
C21	11/12/2019	14/12/2019	13/01/2020	11/02/2020	26/02/2020	05/03/2020	12/03/2020	20/03/2020	26/03/2020
C22	10/01/2020	19/01/2020	14/02/2020	13/03/2020	27/03/2020	06/04/2020	17/04/2020	24/04/2020	30/04/2020
C23	12/02/2020	15/02/2020	16/03/2020	14/04/2020	29/04/2020	07/05/2020	14/05/2020	20/05/2020	28/05/2020
C24	06/03/2020	14/03/2020	15/04/2020	13/05/2020	27/05/2020	04/06/2020	11/06/2020	19/06/2020	25/06/2020

	Deadline for Submission (*)	Start date	Individual PRAC Rapporteurs/ Lead MSs AR (~)	Preliminary PRAC Rapporteur Joint AR	Comments from PRAC/MAH	Updated PRAC Rapporteur Joint AR (#)	PRAC conclusion	CAT adoption	CHMP adoption (^)
C25	08/04/2020	11/04/2020	11/05/2020	09/06/2020	24/06/2020	02/07/2020	09/07/2020	17/07/2020	23/07/2020
C26									
C27	04/06/2020	07/06/2020	06/07/2020	04/08/2020	19/08/2020	27/08/2020	04/09/2020	11/09/2020	17/09/2020
C28	01/07/2020	04/07/2020	03/08/2020	01/09/2020	16/09/2020	24/09/2020	01/10/2020	09/10/2020	15/10/2020
C29	29/07/2020	01/08/2020	01/09/2020	29/09/2020	14/10/2020	22/10/2020	29/10/2020	06/11/2020	12/11/2020
C30	26/08/2020	29/08/2020	28/09/2020	27/10/2020	11/11/2020	19/11/2020	26/11/2020	04/12/2020	10/12/2020
C31	14/10/2020	17/10/2020	16/11/2020	15/12/2020	04/01/2021	07/01/2021	14/01/2021	22/01/2021	28/01/2021
C32	11/11/2020	14/11/2020	14/12/2020	12/01/2021	27/01/2021	04/02/2021	11/02/2021	19/02/2021	25/02/2021
C33	09/12/2020	12/12/2020	11/01/2021	09/02/2021	24/02/2021	04/03/2021	11/03/2021	19/03/2021	25/03/2021
C34	07/01/2021	10/01/2021	08/02/2021	09/03/2021	24/03/2021	31/03/2021	09/04/2021	16/04/2021	22/04/2021
C35	03/02/2021	06/02/2021	08/03/2021	06/04/2021	21/04/2021	29/04/2021	06/05/2021	12/05/2021	20/05/2021
C36	10/03/2021	13/03/2021	12/04/2021	11/05/2021	26/05/2021	03/06/2021	10/06/2021	18/06/2021	24/06/2021
C37	07/04/2021	10/04/2021	10/05/2021	08/06/2021	23/06/2021	01/07/2021	08/07/2021	16/07/2021	22/07/2021
C38									
C39	03/06/2021	06/06/2021	05/07/2021	03/08/2021	18/08/2021	26/08/2021	03/09/2021	10/09/2021	16/09/2021
C40	30/06/2021	03/07/2021	02/08/2021	31/08/2021	15/09/2021	23/09/2021	30/09/2021	08/10/2021	14/10/2021
C41	28/07/2021	31/07/2021	31/08/2021	28/09/2021	13/10/2021	21/10/2021	28/10/2021	05/11/2021	11/11/2021
C42	01/09/2021	04/09/2021	04/10/2021	03/11/2021	17/11/2021	25/11/2021	02/12/2021	10/12/2021	16/12/2021

(~) The applicability of a 90-, 60- or 30-day timetable will be specified at the time of the preceding RSI.

(~) A Lead Member State (MS) is nominated in case of signals affecting only Nationally Authorised Products (NAPs) in order to carry out the preliminary assessment. This is in contrast to signals involving Centrally Authorised Products (CAPs) where the PRAC Rapporteurs of the CAPs circulate individual assessment reports which a nominated overall PRAC Rapporteur consolidates in a joint preliminary assessment report.

(*) 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.

(#) An updated AR is optional and dependent on the comments received from PRAC members and Marketing authorisation Holders (MAHs) which create the need for the update.

(^) A CHMP adoption step applies only in case of PRAC recommendation for variation to the terms of marketing authorisations of centrally authorised products.