



12 October 2018
EMA/500653/2012 Rev 2
Human Medicines Evaluation Division

Timetable¹ Safety referrals (Art 107i, urgent Union procedure)

Submission date(*)	Start date	PRAC (Co) Rapporteur Preliminary Assessment Report	Comments from PRAC & CHMP/CMDh members (**)	PRAC (Co) Rapporteur final Assessment Report	PRAC Recommendation	CHMP Opinion / CMDh position
12/11/2018	19/11/2018	14/12/2018	01/01/2019	07/01/2019	17/01/2019	31/01/2019
10/12/2018	17/12/2018	11/01/2019	29/01/2019	04/02/2019	14/02/2019	28/02/2019
07/01/2019	14/01/2019	08/02/2019	27/02/2019	04/03/2019	14/03/2019	28/03/2019
04/02/2019	11/02/2019	08/03/2019	27/03/2019	01/04/2019	11/04/2019	26/04/2019
11/03/2019	18/03/2019	12/04/2019	01/05/2019	06/05/2019	16/05/2019	29/05/2019
09/04/2019	16/04/2019	10/05/2019	30/05/2019	04/06/2019	14/06/2019	27/06/2019
06/05/2019	13/05/2019	07/06/2019	26/06/2019	01/07/2019	11/07/2019	25/07/2019
03/06/2019	10/06/2019	05/07/2019	24/07/2019	29/07/2019	08/08/2019	22/08/2019***
01/07/2019	08/07/2019	02/08/2019	21/08/2019	27/08/2019	05/09/2019	19/09/2019

¹ This timetable may be subject to revision



Submission date(*)	Start date	PRAC (Co) Rapporteur Preliminary Assessment Report	Comments from PRAC & CHMP/CMDh members (**)	PRAC (Co) Rapporteur final Assessment Report	PRAC Recommendation	CHMP Opinion / CMDh position
29/07/2019	05/08/2019	30/08/2019	18/09/2019	23/09/2019	03/10/2019	17/10/2019
26/08/2019	02/09/2019	27/09/2019	16/10/2019	21/10/2019	31/10/2019	14/11/2019
23/09/2019	30/09/2019	25/10/2019	13/11/2019	18/11/2019	28/11/2019	06/01/2020
11/11/2019	18/11/2019	13/12/2019	01/01/2020	06/01/2020	16/01/2020	30/01/2020
09/12/2019	16/12/2019	10/01/2020	29/01/2020	03/02/2020	13/02/2020	27/02/2020
06/01/2020	13/01/2020	07/02/2020	26/02/2020	02/03/2020	12/03/2020	26/03/2020
11/02/2020	18/02/2020	13/03/2020	02/04/2020	07/04/2020	17/04/2020	30/04/2020
09/03/2020	16/03/2020	08/04/2020	29/04/2020	04/05/2020	14/05/2020	28/05/2020
06/04/2020	13/04/2020	08/05/2020	27/05/2020	02/06/2020	11/06/2020	25/06/2020
04/05/2020	11/05/2020	05/06/2020	24/06/2020	29/06/2020	09/07/2020	23/07/2020
01/06/2020	08/06/2020	03/07/2020	22/07/2020	27/07/2020	06/08/2020	20/08/2020***
30/06/2020	07/07/2020	31/07/2020	20/08/2020	25/08/2020	04/09/2020	17/09/2020
27/07/2020	03/08/2020	28/08/2020	16/09/2020	21/09/2020	01/10/2020	15/10/2020
24/08/2020	31/08/2020	25/09/2020	14/10/2020	19/10/2020	29/10/2020	12/11/2020
21/09/2020	28/09/2020	23/10/2020	11/11/2020	16/11/2020	26/11/2020	10/12/2020
09/11/2020	16/11/2020	11/12/2020	30/12/2020	04/01/2021	14/01/2021	28/01/2021
07/12/2020	14/12/2020	08/01/2021	27/01/2021	01/02/2021	11/02/2021	25/02/2021
04/01/2021	11/01/2021	05/02/2021	24/02/2021	01/03/2021	11/03/2021	25/03/2021
02/02/2021	09/02/2021	05/03/2021	25/03/2021	30/03/2021	09/04/2021	22/04/2021
01/03/2021	08/03/2021	31/03/2021	21/04/2021	26/04/2021	06/05/2021	20/05/2021
05/04/2021	12/04/2021	07/05/2021	26/05/2021	31/05/2021	10/06/2021	24/06/2021
03/05/2021	10/05/2021	04/06/2021	23/06/2021	28/06/2021	08/07/2021	22/07/2021
31/05/2021	07/06/2021	02/07/2021	21/07/2021	26/07/2021	05/08/2021	19/08/2021***
29/06/2021	06/07/2021	30/07/2021	19/08/2021	24/08/2021	03/09/2021	16/09/2021

Submission date(*)	Start date	PRAC (Co) Rapporteur Preliminary Assessment Report	Comments from PRAC & CHMP/CMDh members (**)	PRAC (Co) Rapporteur final Assessment Report	PRAC Recommendation	CHMP Opinion / CMDh position
23/08/2021	30/08/2021	24/09/2021	13/10/2021	18/10/2021	28/10/2021	14/10/2021
27/09/2021	04/10/2021	29/10/2021	17/11/2021	22/11/2021	02/12/2021	11/11/2021
27/09/2021	04/10/2021	29/10/2021	17/11/2021	22/11/2021	02/12/2021	16/12/2021

(*) 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

(**) Comments from PRAC/CMDh/CHMP members are not made available to marketing authorisation holders

(***) Decision to be taken on whether August meetings can be replaced by written procedure as needed