



12 October 2018
EMA/211664/2015 Rev 2
Human Medicines Evaluation Division

Timetable Safety referrals (Art 20 and Art 31PhV¹)

1. Standard Timetable for PRAC List of Questions/List of Outstanding Issues

PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*) ⁱ	Clock restart	(Co-)Rapporteur Assessment Report	Comments (**) ⁱⁱ	Updated (Co-) Rapporteur Assessment Reports	PRAC meeting: Recommendation or LoOI
31/10/2018	27/12/2018	17/01/2019	25/01/2019	01/02/2019	07/02/2019	14/02/2019
29/11/2018	24/01/2019	14/02/2019	22/02/2019	01/03/2019	07/03/2019	14/03/2019
17/01/2019	21/02/2019	14/03/2019	22/03/2019	29/03/2019	04/04/2019	11/04/2019
14/02/2019	28/03/2019	18/04/2019	26/04/2019	03/05/2019	10/05/2019	16/05/2019
14/03/2019	26/04/2019	17/05/2019	25/05/2019	03/06/2019	07/06/2019	14/06/2019
11/04/2019	23/05/2019	13/06/2019	21/06/2019	28/06/2019	04/07/2019	11/07/2019
16/05/2019	20/06/2019	11/07/2019	19/07/2019	26/07/2019	01/08/2019	08/08/2019
14/06/2019	18/07/2019	08/08/2019	16/08/2019	23/08/2019	29/08/2019	05/09/2019
11/07/2019	15/08/2019	05/09/2019	13/09/2019	20/09/2019	26/09/2019	03/10/2019

¹ Timetable for Art 107i referral can be found here: https://www.ema.europa.eu/documents/other/timetable-safety-referral-article-107i-urgent-union-procedure_en.pdf



PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*) ⁱ	Clock restart	(Co-)Rapporteur Assessment Report	Comments (**) ⁱⁱ	Updated (Co-) Rapporteur Assessment Reports	PRAC meeting: Recommendation or LoOI
08/08/2019	12/09/2019	03/10/2019	11/10/2019	18/10/2019	24/10/2019	31/10/2019
05/09/2019	10/10/2019	31/10/2019	08/11/2019	15/11/2019	21/11/2019	28/11/2019
03/10/2019	28/11/2019	19/12/2019	20/12/2019	03/01/2020	09/01/2020	16/01/2020
31/10/2019	26/12/2019	16/01/2020	24/01/2020	31/01/2020	06/02/2020	13/02/2020
28/11/2019	23/01/2020	13/02/2020	21/02/2020	28/02/2020	05/03/2020	12/03/2020
16/01/2020	28/02/2020	20/03/2020	27/03/2020	03/04/2020	08/04/2020	17/04/2020
13/02/2020	26/03/2020	16/04/2020	24/04/2020	01/05/2020	07/05/2020	14/05/2020
12/03/2020	23/04/2020	14/05/2020	20/05/2020	27/05/2020	04/06/2020	11/06/2020
17/04/2020	21/05/2020	11/06/2020	19/06/2020	26/06/2020	02/07/2020	09/07/2020
14/05/2020	18/06/2020	09/07/2020	17/07/2020	24/07/2020	30/07/2020	06/08/2020
11/06/2020	17/07/2020	07/08/2020	14/08/2020	21/08/2020	28/08/2020	04/09/2020
09/07/2020	13/08/2020	03/09/2020	11/09/2020	18/09/2020	24/09/2020	01/10/2020
06/08/2020	10/09/2020	01/10/2020	09/10/2020	16/10/2020	22/10/2020	29/10/2020
04/09/2020	08/10/2020	29/10/2020	06/11/2020	13/11/2020	19/11/2020	26/11/2020
01/10/2020	26/11/2020	17/12/2020	22/12/2020	04/01/2021	07/01/2021	14/01/2021
29/10/2020	24/12/2020	14/01/2021	22/01/2021	29/01/2021	04/02/2021	11/02/2021
26/11/2020	21/01/2021	11/02/2021	19/02/2021	26/02/2021	04/03/2021	11/03/2021
14/01/2021	19/02/2021	12/03/2021	19/03/2021	25/03/2021	31/03/2021	09/04/2021
11/02/2021	18/03/2021	08/04/2021	16/04/2021	23/04/2021	29/04/2021	06/05/2021
11/03/2021	22/04/2021	13/05/2021	21/05/2021	28/05/2021	03/06/2021	10/06/2021
09/04/2021	20/05/2021	10/06/2021	18/06/2021	25/06/2021	01/07/2021	08/07/2021
06/05/2021	17/06/2021	08/07/2021	16/07/2021	23/07/2021	29/07/2021	05/08/2021
10/06/2021	16/07/2021	06/08/2021	13/08/2021	20/08/2021	27/08/2021	03/09/2021
08/07/2021	12/08/2021	02/09/2021	10/09/2021	17/09/2021	23/09/2021	30/09/2021
05/08/2021	10/10/2021	31/10/2021	08/11/2021	15/11/2021	21/11/2021	28/11/2021

2. Shortened Timetable for PRAC List of Questions/List of Outstanding Issues (as applicable)

PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*)	Clock restart	(Co-)Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	PRAC meeting: Recommendation or LoOI
31/10/2018	29/11/2018	20/12/2018	20/12/2018	27/12/2018	10/01/2019	17/01/2019
29/11/2018	27/12/2018	17/01/2019	25/01/2019	01/02/2019	07/02/2019	14/02/2019
17/01/2019	24/01/2019	14/02/2019	22/02/2019	01/03/2019	07/03/2019	14/03/2019
14/02/2019	21/02/2019	14/03/2019	22/03/2019	29/03/2019	04/04/2019	11/04/2019
14/03/2019	28/03/2019	18/04/2019	26/04/2019	03/05/2019	10/05/2019	16/05/2019
11/04/2019	26/04/2019	17/05/2019	23/05/2019	29/05/2019	07/06/2019	14/06/2019
16/05/2019	23/05/2019	13/06/2019	21/06/2019	28/06/2019	04/07/2019	11/07/2019
14/06/2019	20/06/2019	11/07/2019	19/07/2019	26/07/2019	01/08/2019	08/08/2019
11/07/2019	18/07/2019	08/08/2019	16/08/2019	23/08/2019	29/08/2019	05/09/2019
08/08/2019	15/08/2019	05/09/2019	13/09/2019	20/09/2019	26/09/2019	03/10/2019
05/09/2019	12/09/2019	03/10/2019	11/10/2019	18/10/2019	24/10/2019	31/10/2019
03/10/2019	10/10/2019	31/10/2019	08/11/2019	15/11/2019	21/11/2019	28/11/2019
31/10/2019	28/11/2019	19/12/2019	20/12/2019	03/01/2020	09/01/2020	16/01/2020
28/11/2019	26/12/2019	16/01/2020	24/01/2020	31/01/2020	06/02/2020	13/02/2020
16/01/2020	23/01/2020	13/02/2020	21/02/2020	28/02/2020	05/03/2020	12/03/2020
13/02/2020	28/02/2020	20/03/2020	27/03/2020	03/04/2020	08/04/2020	17/04/2020
12/03/2020	26/03/2020	16/04/2020	24/04/2020	01/05/2020	07/05/2020	14/05/2020
17/04/2020	23/04/2020	14/05/2020	20/05/2020	27/05/2020	04/06/2020	11/06/2020
14/05/2020	21/05/2020	11/06/2020	19/06/2020	26/06/2020	02/07/2020	09/07/2020
11/06/2020	18/06/2020	09/07/2020	17/07/2020	24/07/2020	30/07/2020	06/08/2020
09/07/2020	17/07/2020	07/08/2020	14/08/2020	21/08/2020	28/08/2020	04/09/2020
06/08/2020	13/08/2020	03/09/2020	11/09/2020	18/09/2020	24/09/2020	01/10/2020
04/09/2020	10/09/2020	01/10/2020	09/10/2020	16/10/2020	22/10/2020	29/10/2020

PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*)	Clock restart	(Co-)Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	PRAC meeting: Recommendation or LoOI
01/10/2020	08/10/2020	29/10/2020	06/11/2020	13/11/2020	19/11/2020	26/11/2020
29/10/2020	26/11/2020	17/12/2020	22/12/2020	04/12/2020	07/01/2021	14/01/2021
26/11/2020	24/12/2020	14/01/2021	22/01/2021	29/01/2021	04/02/2021	11/02/2021
14/01/2021	21/01/2021	11/02/2021	19/02/2021	26/02/2021	04/03/2021	11/03/2021
11/02/2021	19/02/2021	12/03/2021	19/03/2021	25/03/2021	31/03/2021	09/04/2021
11/03/2021	18/03/2021	08/04/2021	16/04/2021	23/04/2021	29/04/2021	06/05/2021
09/04/2021	22/04/2021	13/05/2021	21/05/2021	28/05/2021	03/06/2021	10/06/2021
06/05/2021	20/05/2021	10/06/2021	18/06/2021	25/06/2021	01/07/2021	08/07/2021
10/06/2021	17/06/2021	08/07/2021	16/07/2021	23/07/2021	29/07/2021	05/08/2021
08/07/2021	16/07/2021	06/08/2021	13/08/2021	20/08/2021	27/08/2021	03/09/2021
05/08/2021	12/08/2021	02/09/2021	10/09/2021	17/09/2021	23/09/2021	30/09/2021
03/09/2021	10/10/2021	31/10/2021	08/11/2021	15/11/2021	22/11/2021	28/11/2021
30/09/2021	14/10/2021	04/11/2021	12/11/2021	19/11/2021	25/11/2021	02/12/2021

3. Swift Timetable for final PRAC List of Outstanding Issues (as applicable)

PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*)	Clock restart	(Co-)Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	PRAC meeting: Recommendation or LoOI
04/10/2018	09/10/2018	14/10/2018	18/10/2018	31/10/2018	25/10/2018	31/10/2018
31/10/2018	07/11/2018	12/11/2018	16/11/2018	21/11/2018	23/11/2018	29/11/2018
29/11/2018	26/12/2018	31/12/2018	04/01/2019	09/01/2019	11/01/2019	17/01/2019
17/01/2019	23/01/2019	28/01/2019	01/02/2019	06/02/2019	08/02/2019	14/02/2019
14/02/2019	20/02/2019	25/02/2019	01/03/2019	06/03/2019	08/03/2019	14/03/2019
14/03/2019	20/03/2019	25/03/2019	29/03/2019	03/04/2019	05/04/2019	11/04/2019
11/04/2019	24/04/2019	29/04/2019	03/05/2019	08/05/2019	10/05/2019	16/05/2019
16/05/2019	23/05/2019	28/05/2019	29/05/2019	04/06/2019	07/06/2019	14/06/2019
14/06/2019	19/06/2019	24/06/2019	28/06/2019	03/07/2019	05/07/2019	11/07/2019
11/07/2019	17/07/2019	22/07/2019	26/07/2019	31/07/2019	02/08/2019	08/08/2019
08/08/2019	14/08/2019	19/08/2019	23/08/2019	28/08/2019	30/08/2019	05/09/2019
05/09/2019	11/09/2019	16/09/2019	20/09/2019	25/09/2019	27/09/2019	03/10/2019
03/10/2019	09/10/2019	14/10/2019	18/10/2019	23/10/2019	25/10/2019	31/10/2019
31/10/2019	06/11/2019	11/11/2019	15/11/2019	20/11/2019	22/11/2019	28/11/2019
28/11/2019	25/12/2019	30/12/2019	03/01/2020	08/01/2020	10/01/2020	16/01/2020
16/01/2020	22/01/2020	27/01/2020	31/01/2020	05/02/2020	07/02/2020	13/02/2020
13/02/2020	19/02/2020	24/02/2020	28/02/2020	04/03/2020	06/03/2020	12/03/2020
12/03/2020	26/03/2020	31/03/2020	01/04/2020	06/04/2020	08/04/2020	17/04/2020
17/04/2020	22/04/2020	27/04/2020	30/04/2020	06/05/2020	08/05/2020	14/05/2020
14/05/2020	20/05/2020	25/05/2020	29/05/2020	03/06/2020	05/06/2020	11/06/2020
11/06/2020	17/06/2020	22/06/2020	26/06/2020	01/07/2020	03/07/2020	09/07/2020
09/07/2020	15/07/2020	20/07/2020	24/07/2020	29/07/2020	31/07/2020	06/08/2020
06/08/2020	13/08/2020	18/08/2020	21/08/2020	26/08/2020	28/08/2020	04/09/2020
04/09/2020	09/09/2020	14/09/2020	18/09/2020	23/09/2020	25/09/2020	01/10/2020

PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*)	Clock restart	(Co-)Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	PRAC meeting: Recommendation or LoOI
01/10/2020	07/10/2020	12/10/2020	16/10/2020	21/10/2020	23/10/2020	29/10/2020
29/10/2020	04/11/2020	09/11/2020	13/11/2020	18/11/2020	20/11/2020	26/11/2020
26/11/2020	23/12/2020	28/12/2020	04/01/2021	06/01/2021	08/01/2021	14/01/2021
14/01/2021	20/01/2021	25/01/2021	29/01/2021	03/02/2021	05/02/2021	11/02/2021
11/02/2021	17/02/2021	22/02/2021	26/02/2021	03/03/2021	05/03/2021	11/03/2021
11/03/2021	18/03/2021	23/03/2021	24/03/2021	29/03/2021	31/03/2021	09/04/2021
09/04/2021	14/04/2021	19/04/2021	23/04/2021	28/04/2021	30/04/2021	06/05/2021
06/05/2021	19/05/2021	24/05/2021	28/05/2021	02/06/2021	04/06/2021	10/06/2021
10/06/2021	16/06/2021	21/06/2021	25/06/2021	30/06/2021	02/07/2021	08/07/2021
08/07/2021	14/07/2021	19/07/2021	23/07/2021	28/07/2021	30/07/2021	05/08/2021
05/08/2021	12/08/2021	17/08/2021	20/08/2021	25/08/2021	27/08/2021	03/09/2021
03/09/2021	08/09/2021	13/09/2021	17/09/2021	22/09/2021	24/09/2021	30/09/2021
30/09/2021	06/11/2021	11/11/2021	15/11/2021	19/11/2021	22/11/2021	28/11/2021
28/11/2021	10/11/2021	15/11/2021	19/11/2021	24/11/2021	26/11/2021	02/12/2021

ⁱ (*) 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.

ⁱⁱ (**) Comments from members are not made available to Marketing Authorisation Holder(s)