



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2023
EMA/29545/2021 rev.1
Human Medicines 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(*)	Clock restart	(Co-)Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	PRAC meeting: Recommendation or LoOI
14/04/2023	18/05/2023	08/06/2023	15/06/2023	22/06/2023	28/06/2023	06/07/2023
12/05/2023	15/06/2023	06/07/2023	13/07/2023	20/07/2023	26/07/2023	03/08/2023***
08/06/2023	13/07/2023	03/08/2023	10/08/2023	17/08/2023	23/08/2023	31/08/2023
06/07/2023	10/08/2023	31/08/2023	07/09/2023	14/09/2023	20/09/2023	28/09/2023
03/08/2023***	07/09/2023	28/09/2023	05/10/2023	12/10/2023	18/10/2023	26/10/2023
31/08/2023	12/10/2023	02/11/2023	09/11/2023	16/11/2023	22/11/2023	30/11/2023

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(*)	Clock restart	(Co-)Rapporteur Assessment Report	Comments (**)	Updated (Co-) Rapporteur Assessment Reports	PRAC meeting: Recommendation or LoOI
28/09/2023	23/11/2023	14/12/2023	21/12/2023	28/12/2023	03/01/2024	11/01/2024
26/10/2023	21/12/2023	11/01/2024	18/01/2024	25/01/2024	31/01/2024	08/02/2024
30/11/2023	18/01/2024	08/02/2024	15/02/2024	22/02/2024	28/02/2024	07/03/2024
11/01/2024	22/02/2024	14/03/2024	20/03/2024	27/03/2024	03/04/2024	11/04/2024
08/02/2024	28/03/2024	18/04/2024	25/04/2024	02/05/2024	08/05/2024	16/05/2024
07/03/2024	25/04/2024	16/05/2024	23/05/2024	30/05/2024	05/06/2024	13/06/2024
11/04/2024	23/05/2024	13/06/2024	20/06/2024	27/06/2024	03/07/2024	11/07/2024
16/05/2024	20/06/2024	11/07/2024	18/07/2024	25/07/2024	31/07/2024	08/08/2024***
13/06/2024	18/07/2024	08/08/2024	16/08/2024	22/08/2024	28/08/2024	05/09/2024
11/07/2024	15/08/2024	05/09/2024	12/09/2024	19/09/2024	25/09/2024	03/10/2024
08/08/2024***	12/09/2024	03/10/2024	10/10/2024	17/10/2024	23/10/2024	31/10/2024
05/09/2024	10/10/2024	31/10/2024	07/11/2024	14/11/2024	20/11/2024	28/11/2024
03/10/2024	28/11/2024	19/12/2024	26/12/2024	02/01/2025	08/01/2025	16/01/2025
31/10/2024	26/12/2024	16/01/2025	23/01/2025	30/01/2025	05/02/2025	13/02/2025
28/11/2024	23/01/2025	13/02/2025	20/02/2025	27/02/2025	05/03/2025	13/03/2025
16/01/2025	20/02/2025	13/03/2025	20/03/2025	27/03/2025	02/04/2025	10/04/2025
13/02/2025	20/03/2025	10/04/2025	16/04/2025	24/04/2025	30/04/2025	08/05/2025
13/03/2025	17/04/2025	08/05/2025	15/05/2025	22/05/2025	28/05/2025	05/06/2025
10/04/2025	22/05/2025	12/06/2025	19/06/2025	26/06/2025	02/07/2025	10/07/2025
08/05/2025	19/06/2025	10/07/2025	17/07/2025	24/07/2025	30/07/2025	07/08/2025***
05/06/2025	17/07/2025	07/08/2025	14/08/2025	21/08/2025	27/08/2025	04/09/2025
10/07/2025	14/08/2025	04/09/2025	11/09/2025	18/09/2025	24/09/2025	02/10/2025
07/08/2025***	11/09/2025	02/10/2025	09/10/2025	16/10/2025	22/10/2025	30/10/2025
04/09/2025	09/10/2025	30/10/2025	06/11/2025	13/11/2025	19/11/2025	27/11/2025
02/10/2025	27/11/2025	18/12/2025	26/12/2025	02/01/2026	07/01/2026	15/01/2026
30/10/2025	26/12/2025	15/01/2026	22/01/2026	29/01/2026	04/02/2026	12/02/2026

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
27/11/2025	22/01/2026	12/02/2026	19/02/2026	26/02/2026	04/03/2026	12/03/2026
15/01/2026	20/02/2026	13/03/2026	19/03/2026	26/03/2026	01/04/2026	10/04/2026
12/02/2026	19/03/2026	09/04/2026	16/04/2026	23/04/2026	29/04/2026	07/05/2026
12/03/2026	23/04/2026	14/05/2026	21/05/2026	28/05/2026	03/06/2026	11/06/2026
10/04/2026	21/05/2026	11/06/2026	18/06/2026	25/06/2026	01/07/2026	09/07/2026
07/05/2026	18/06/2026	09/07/2026	16/07/2026	23/07/2026	29/07/2026	06/08/2026***
11/06/2026	16/07/2026	06/08/2026	13/08/2026	20/08/2026	26/08/2026	03/09/2026
09/07/2026	13/08/2026	03/09/2026	10/09/2026	17/09/2026	23/09/2026	01/10/2026
06/08/2026***	10/09/2026	01/10/2026	08/10/2026	15/10/2026	21/10/2026	29/10/2026
03/09/2026	08/10/2026	29/10/2026	05/11/2026	12/11/2026	18/11/2026	26/11/2026

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
12/05/2023	25/05/2023	08/06/2023	16/06/2023	22/06/2023	28/06/2023	06/07/2023
08/06/2023	22/06/2023	06/07/2023	14/07/2023	20/07/2023	26/07/2023	03/08/2023***
06/07/2023	20/07/2023	03/08/2023	11/08/2023	17/08/2023	23/08/2023	31/08/2023
03/08/2023***	17/08/2023	31/08/2023	08/09/2023	14/09/2023	20/09/2023	28/09/2023
31/08/2023	14/09/2023	28/09/2023	06/10/2023	12/10/2023	18/10/2023	26/10/2023
28/09/2023	19/10/2023	02/11/2023	10/11/2023	16/11/2023	22/11/2023	30/11/2023
26/10/2023	30/11/2023	14/12/2023	22/12/2023	28/12/2023	03/01/2024	11/01/2024

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
30/11/2023	28/12/2023	11/01/2024	19/01/2024	25/01/2024	31/01/2024	08/02/2024
11/01/2024	25/01/2024	08/02/2024	16/02/2024	22/02/2024	28/02/2024	07/03/2024
08/02/2024	29/02/2024	14/03/2024	22/03/2024	27/03/2024	03/04/2024	11/04/2024
07/03/2024	04/04/2024	18/04/2024	26/04/2024	02/05/2024	08/05/2024	16/05/2024
11/04/2024	02/05/2024	16/05/2024	24/05/2024	30/05/2024	05/06/2024	13/06/2024
16/05/2024	30/05/2024	13/06/2024	21/06/2024	27/06/2024	03/07/2024	11/07/2024
13/06/2024	27/06/2024	11/07/2024	19/07/2024	25/07/2024	31/07/2024	08/08/2024***
11/07/2024	25/07/2024	08/08/2024	16/08/2024	22/08/2024	28/08/2024	05/09/2024
08/08/2024***	22/08/2024	05/09/2024	13/09/2024	19/09/2024	25/09/2024	03/10/2024
05/09/2024	19/09/2024	03/10/2024	11/10/2024	17/10/2024	23/10/2024	31/10/2024
03/10/2024	17/10/2024	31/10/2024	08/11/2024	14/11/2024	20/11/2024	28/11/2024
31/10/2024	05/12/2024	19/12/2024	27/12/2024	02/01/2025	08/01/2025	16/01/2025
28/11/2024	02/01/2025	16/01/2025	24/01/2025	30/01/2025	05/02/2025	13/02/2025
16/01/2025	30/01/2025	13/02/2025	21/02/2025	27/02/2025	05/03/2025	13/03/2025
13/02/2025	27/02/2025	13/03/2025	21/03/2025	27/03/2025	02/04/2025	10/04/2025
13/03/2025	27/03/2025	10/04/2025	16/04/2025	24/04/2025	30/04/2025	08/05/2025
10/04/2025	24/04/2025	08/05/2025	16/05/2025	22/05/2025	28/05/2025	05/06/2025
08/05/2025	29/05/2025	12/06/2025	20/06/2025	26/06/2025	02/07/2025	10/07/2025
05/06/2025	26/06/2025	10/07/2025	18/07/2025	24/07/2025	30/07/2025	07/08/2025***
10/07/2025	24/07/2025	07/08/2025	14/08/2025	21/08/2025	27/08/2025	04/09/2025
07/08/2025***	21/08/2025	04/09/2025	12/09/2025	18/09/2025	24/09/2025	02/10/2025
04/09/2025	18/09/2025	02/10/2025	10/10/2025	16/10/2025	22/10/2025	30/10/2025
02/10/2025	16/10/2025	30/10/2025	07/11/2025	13/11/2025	19/11/2025	27/11/2025
30/10/2025	04/12/2025	18/12/2025	26/12/2025	02/01/2026	08/01/2026	15/01/2026
27/11/2025	01/01/2026	15/01/2026	23/01/2026	29/01/2026	04/02/2026	12/02/2026
15/01/2026	29/01/2026	12/02/2026	20/02/2026	26/02/2026	04/03/2026	12/03/2026

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
12/02/2026	27/02/2026	13/03/2026	20/03/2026	27/03/2026	01/04/2026	10/04/2026
12/03/2026	26/03/2026	09/04/2026	17/04/2026	23/04/2026	29/04/2026	07/05/2026
10/04/2026	30/04/2026	14/05/2026	22/05/2026	28/05/2026	03/06/2026	11/06/2026
07/05/2026	28/05/2026	11/06/2026	19/06/2026	25/06/2026	01/07/2026	09/07/2026
11/06/2026	25/06/2026	09/07/2026	17/07/2026	23/07/2026	29/07/2026	06/08/2026***
09/07/2026	23/07/2026	06/08/2026	14/08/2026	20/08/2026	26/08/2026	03/09/2026
06/08/2026***	20/08/2026	03/09/2026	11/09/2026	17/09/2026	23/09/2026	01/10/2026
03/09/2026	17/09/2026	01/10/2026	09/10/2026	15/10/2026	21/10/2026	29/10/2026

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
08/06/2023	14/06/2023	19/06/2023	22/06/2023	27/06/2023	29/06/2023	06/07/2023
06/07/2023	12/07/2023	17/07/2023	20/07/2023	25/07/2023	27/07/2023	03/08/2023***
03/08/2023***	09/08/2023	14/08/2023	17/08/2023	22/08/2023	24/08/2023	31/08/2023
31/08/2023	06/09/2023	11/09/2023	14/09/2023	19/09/2023	21/09/2023	28/09/2023
28/09/2023	04/10/2023	09/10/2023	12/10/2023	17/10/2023	19/10/2023	26/10/2023
26/10/2023	08/11/2023	13/11/2023	16/11/2023	21/11/2023	23/11/2023	30/11/2023
30/11/2023	20/12/2023	25/12/2023	28/12/2023	03/01/2024	05/01/2024	11/01/2024
11/01/2024	17/01/2024	22/01/2024	25/01/2024	30/01/2024	01/02/2024	08/02/2024
08/02/2024	14/02/2024	19/02/2024	22/02/2024	27/02/2024	29/02/2024	07/03/2024
07/03/2024	20/03/2024	25/03/2024	27/03/2024	03/04/2024	05/04/2024	11/04/2024

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
11/04/2024	24/04/2024	29/04/2024	02/05/2024	06/05/2024	08/05/2024	16/05/2024
16/05/2024	22/05/2024	27/05/2024	30/05/2024	04/06/2024	06/06/2024	13/06/2024
13/06/2024	19/06/2024	24/06/2024	27/06/2024	02/07/2024	04/07/2024	11/07/2024
11/07/2024	17/07/2024	22/07/2024	25/07/2024	30/07/2024	01/08/2024	08/08/2024***
08/08/2024***	14/08/2024	19/08/2024	22/08/2024	27/08/2024	29/08/2024	05/09/2024
05/09/2024	11/09/2024	16/09/2024	19/09/2024	24/09/2024	26/09/2024	03/10/2024
03/10/2024	09/10/2024	14/10/2024	17/10/2024	22/10/2024	24/10/2024	31/10/2024
31/10/2024	06/11/2024	11/11/2024	14/11/2024	19/11/2024	21/11/2024	28/11/2024
28/11/2024	25/12/2024	30/12/2024	02/01/2025	07/01/2025	09/01/2025	16/01/2025
16/01/2025	22/01/2025	27/01/2025	30/01/2025	04/02/2025	06/02/2025	13/02/2025
13/02/2025	19/02/2025	24/02/2025	27/02/2025	04/03/2025	06/03/2025	13/03/2025
13/03/2025	19/03/2025	24/03/2025	27/03/2025	01/04/2025	03/04/2025	10/04/2025
10/04/2025	16/04/2025	21/04/2025	24/04/2025	29/04/2025	02/05/2025	08/05/2025
08/05/2025	14/05/2025	19/05/2025	22/05/2025	26/05/2025	28/05/2025	05/06/2025
05/06/2025	18/06/2025	23/06/2025	26/06/2025	01/07/2025	03/07/2025	10/07/2025
10/07/2025	16/07/2025	21/07/2025	24/07/2025	29/07/2025	31/07/2025	07/08/2025***
07/08/2025***	13/08/2025	18/08/2025	21/08/2025	26/08/2025	28/08/2025	04/09/2025
04/09/2025	10/09/2025	15/09/2025	18/09/2025	23/09/2025	25/09/2025	02/10/2025
02/10/2025	08/10/2025	13/10/2025	16/10/2025	21/10/2025	23/10/2025	30/10/2025
30/10/2025	05/11/2025	10/11/2025	13/11/2025	18/11/2025	20/11/2025	27/11/2025
27/11/2025	24/12/2025	29/12/2025	02/01/2026	06/01/2026	08/01/2026	15/01/2026
15/01/2026	21/01/2026	26/01/2026	29/01/2026	03/02/2026	05/02/2026	12/02/2026
12/02/2026	18/02/2026	23/02/2026	26/02/2026	03/03/2026	05/03/2026	12/03/2026
12/03/2026	19/03/2026	24/03/2026	27/03/2026	30/03/2026	01/04/2026	10/04/2026
10/04/2026	15/04/2026	20/04/2026	23/04/2026	28/04/2026	30/04/2026	07/05/2026
07/05/2026	20/05/2026	25/05/2026	28/05/2026	02/06/2026	04/06/2026	11/06/2026

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
11/06/2026	17/06/2026	22/06/2026	25/06/2026	30/06/2026	02/07/2026	09/07/2026
09/07/2026	15/07/2026	20/07/2026	23/07/2026	28/07/2026	30/07/2026	06/08/2026***
06/08/2026***	12/08/2026	17/08/2026	20/08/2026	25/08/2026	27/08/2026	03/09/2026
03/09/2026	09/09/2026	14/09/2026	17/09/2026	22/09/2026	24/09/2026	01/10/2026
01/10/2026	07/10/2026	12/10/2026	15/10/2026	20/10/2026	22/10/2026	29/10/2026
29/10/2026	04/11/2026	09/11/2026	12/11/2026	17/11/2026	19/11/2026	26/11/2026

(*)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 members are not made available to Marketing Authorisation Holder(s) at that stage

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