



12 February 2026
EMA/397814/2025

Human Medicines Division

The timetables in this document may be subject to revision

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(s)	Comments (**)	Updated (Co-) Rapporteur Assessment Report(s)	PRAC meeting: Recommendation or LoOI
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
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

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

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands

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PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*)	Clock restart	(Co-)Rapporteur Assessment Report(s)	Comments (**)	Updated (Co-) Rapporteur Assessment Report(s)	PRAC meeting: Recommendation or LoOI
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
01/10/2026	26/11/2026	17/12/2026	24/12/2026	31/12/2026	06/01/2027	14/01/2027
29/10/2026	24/12/2026	14/01/2027	21/01/2027	28/01/2027	03/02/2027	11/02/2027
26/11/2026	28/01/2027	18/02/2027	25/02/2027	04/03/2027	10/03/2027	18/03/2027
14/01/2027	25/02/2027	18/03/2027	24/03/2027	01/04/2027	07/04/2027	15/04/2027
11/02/2027	25/03/2027	15/04/2027	22/04/2027	29/04/2027	05/05/2027	13/05/2027
18/03/2027	22/04/2027	13/05/2027	20/05/2027	27/05/2027	02/06/2027	10/06/2027
15/04/2027	20/05/2027	10/06/2027	17/06/2027	24/06/2027	30/06/2027	08/07/2027
13/05/2027	17/06/2027	08/07/2027	15/07/2027	22/07/2027	28/07/2027	05/08/2027***
10/06/2027	15/07/2027	05/08/2027	12/08/2027	19/08/2027	25/08/2027	02/09/2027
08/07/2027	12/08/2027	02/09/2027	09/09/2027	16/09/2027	22/09/2027	30/09/2027
05/08/2027	09/09/2027	30/09/2027	07/10/2027	14/10/2027	20/10/2027	28/10/2027
02/09/2027	14/10/2027	04/11/2027	11/11/2027	18/11/2027	24/11/2027	02/12/2027
30/09/2027	25/11/2027	16/12/2027	23/12/2027	30/12/2027	05/01/2028	13/01/2028
28/10/2027	23/12/2027	13/01/2028	20/01/2028	27/01/2028	02/02/2028	10/02/2028
02/12/2027	20/01/2028	10/02/2028	17/02/2028	24/02/2028	01/03/2028	09/03/2028
13/01/2028	17/02/2028	09/03/2028	16/03/2028	23/03/2028	29/03/2028	06/04/2028
10/02/2028	17/03/2028	07/04/2028	18/04/2028	24/04/2028	28/04/2028	05/05/2028
09/03/2028	21/04/2028	12/05/2028	19/05/2028	24/05/2028	01/06/2028	09/06/2028
06/04/2028	18/05/2028	08/06/2028	15/06/2028	22/06/2028	28/06/2028	06/07/2028

PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*)	Clock restart	(Co-)Rapporteur Assessment Report(s)	Comments (**)	Updated (Co-) Rapporteur Assessment Report(s)	PRAC meeting: Recommendation or LoOI
05/05/2028	15/06/2028	06/07/2028	13/07/2028	20/07/2028	26/07/2028	03/08/2028***
09/06/2028	13/07/2028	03/08/2028	10/08/2028	17/08/2028	23/08/2028	31/08/2028
06/07/2028	10/08/2028	31/08/2028	07/09/2028	14/09/2028	20/09/2028	28/09/2028
03/08/2028	07/09/2028	28/09/2028	05/10/2028	12/10/2028	18/10/2028	26/10/2028
31/08/2028	12/10/2028	02/11/2028	09/11/2028	16/11/2028	22/11/2028	30/11/2028

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(s)	Comments (**)	Updated (Co-) Rapporteur Assessment Report(s)	PRAC meeting: Recommendation or LoOI
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
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

PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*)	Clock restart	(Co-)Rapporteur Assessment Report(s)	Comments (**)	Updated (Co-) Rapporteur Assessment Report(s)	PRAC meeting: Recommendation or LoOI
01/10/2026	15/10/2026	29/10/2026	06/11/2026	12/11/2026	18/11/2026	26/11/2026
29/10/2026	03/12/2026	17/12/2026	24/12/2026	31/12/2026	06/01/2027	14/01/2027
26/11/2026	31/12/2026	14/01/2027	22/01/2027	28/01/2027	03/02/2027	11/02/2027
14/01/2027	04/02/2027	18/02/2027	26/02/2027	04/03/2027	10/03/2027	18/03/2027
11/02/2027	04/03/2027	18/03/2027	24/03/2027	01/04/2027	07/04/2027	15/04/2027
18/03/2027	01/04/2027	15/04/2027	23/04/2027	29/04/2027	05/05/2027	13/05/2027
15/04/2027	29/04/2027	13/05/2027	21/05/2027	27/05/2027	02/06/2027	10/06/2027
13/05/2027	27/05/2027	10/06/2027	18/06/2027	24/06/2027	30/06/2027	08/07/2027
10/06/2027	24/06/2027	08/07/2027	16/07/2027	22/07/2027	28/07/2027	05/08/2027***
08/07/2027	22/07/2027	05/08/2027	13/08/2027	19/08/2027	25/08/2027	02/09/2027
05/08/2027	19/08/2027	02/09/2027	10/09/2027	16/09/2027	22/09/2027	30/09/2027
02/09/2027	16/09/2027	30/09/2027	08/10/2027	14/10/2027	20/10/2027	28/10/2027
30/09/2027	21/10/2027	04/11/2027	12/11/2027	18/11/2027	24/11/2027	02/12/2027
28/10/2027	02/12/2027	16/12/2027	24/12/2027	30/12/2027	05/01/2028	13/01/2028
02/12/2027	30/12/2027	13/01/2028	21/01/2028	27/01/2028	02/02/2028	10/02/2028
13/01/2028	27/01/2028	10/02/2028	18/02/2028	24/02/2028	01/03/2028	09/03/2028
10/02/2028	24/02/2028	09/03/2028	17/03/2028	23/03/2028	29/03/2028	06/04/2028
09/03/2028	22/03/2028	05/04/2028	12/04/2028	19/04/2028	26/04/2028	05/05/2028
06/04/2028	27/04/2028	11/05/2028	19/05/2028	24/05/2028	01/06/2028	09/06/2028
05/05/2028	25/05/2028	08/06/2028	16/06/2028	22/06/2028	28/06/2028	06/07/2028
09/06/2028	22/06/2028	06/07/2028	14/07/2028	20/07/2028	26/07/2028	03/08/2028***
06/07/2028	20/07/2028	03/08/2028	11/08/2028	17/08/2028	23/08/2028	31/08/2028
03/08/2028	17/08/2028	31/08/2028	08/09/2028	14/09/2028	20/09/2028	28/09/2028
31/08/2028	14/09/2028	28/09/2028	06/10/2028	12/10/2028	18/10/2028	26/10/2028
28/09/2028	19/10/2028	02/11/2028	10/11/2028	16/11/2028	22/11/2028	30/11/2028

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(s)	Comments (**)	Updated (Co-) Rapporteur Assessment Report(s)	PRAC meeting: Recommendation or LoOI
27/11/2025	24/12/2025	29/12/2025	05/01/2026	07/01/2026	09/01/2026	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
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
26/11/2026	23/12/2026	28/12/2026	04/01/2027	06/01/2027	08/01/2027	14/01/2027
14/01/2027	20/01/2027	25/01/2027	28/01/2027	02/02/2027	04/02/2027	11/02/2027
11/02/2027	24/02/2027	01/03/2027	04/03/2027	09/03/2027	11/03/2027	18/03/2027
18/03/2027	24/03/2027	29/03/2027	01/04/2027	06/04/2027	08/04/2027	15/04/2027
15/04/2027	21/04/2027	26/04/2027	29/04/2027	03/05/2027	05/05/2027	13/05/2027
13/05/2027	19/05/2027	24/05/2027	27/05/2027	01/06/2027	03/06/2027	10/06/2027
10/06/2027	16/06/2027	21/06/2027	24/06/2027	29/06/2027	01/07/2027	08/07/2027
08/07/2027	14/07/2027	19/07/2027	22/07/2027	27/07/2027	29/07/2027	05/08/2027***
05/08/2027	11/08/2027	16/08/2027	19/08/2027	24/08/2027	26/08/2027	02/09/2027

PRAC meeting: Start/LoQ, clock start and stop	Submission of responses(*)	Clock restart	(Co-)Rapporteur Assessment Report(s)	Comments (**)	Updated (Co-) Rapporteur Assessment Report(s)	PRAC meeting: Recommendation or LoOI
02/09/2027	08/09/2027	13/09/2027	16/09/2027	21/09/2027	23/09/2027	30/09/2027
30/09/2027	06/10/2027	11/10/2027	14/10/2027	19/10/2027	21/10/2027	28/10/2027
28/10/2027	10/11/2027	15/11/2027	18/11/2027	23/11/2027	25/11/2027	02/12/2027
02/12/2027	22/12/2027	27/12/2027	03/01/2028	05/01/2028	07/01/2028	13/01/2028
13/01/2028	19/01/2028	24/01/2028	27/01/2028	01/02/2028	03/02/2028	10/02/2028
10/02/2028	16/02/2028	21/02/2028	24/02/2028	29/02/2028	02/03/2028	09/03/2028
09/03/2028	15/03/2028	20/03/2028	23/03/2028	28/03/2028	30/03/2028	06/04/2028
06/04/2028	13/04/2028	18/04/2028	21/04/2028	26/04/2028	28/04/2028	05/05/2028
05/05/2028	18/05/2028	23/05/2028	29/05/2028	31/05/2028	02/06/2028	09/06/2028
09/06/2028	14/06/2028	19/06/2028	22/06/2028	27/06/2028	29/06/2028	06/07/2028
06/07/2028	12/07/2028	17/07/2028	20/07/2028	25/07/2028	27/07/2028	03/08/2028***
03/08/2028	09/08/2028	14/08/2028	17/08/2028	22/08/2028	24/08/2028	31/08/2028
31/08/2028	06/09/2028	11/09/2028	14/09/2028	19/09/2028	21/09/2028	28/09/2028
28/09/2028	04/10/2028	09/10/2028	12/10/2028	17/10/2028	19/10/2028	26/10/2028
26/10/2028	08/11/2028	13/11/2028	16/11/2028	21/11/2028	23/11/2028	30/11/2028

(*) 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