



13 July 2021  
EMA/29545/2021  
Human Medicines Division

## Timetable Safety referrals (Art 20 and Art 31PhV<sup>1</sup>)

### 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
06/05/2021	17/06/2021	08/07/2021	16/07/2021	23/07/2021	29/07/2021	05/08/2021***
10/06/2021	15/07/2021	05/08/2021	13/08/2021	20/08/2021	26/08/2021	02/09/2021
08/07/2021	12/08/2021	02/09/2021	10/09/2021	17/09/2021	23/09/2021	30/09/2021
05/08/2021***	09/09/2021	30/09/2021	08/10/2021	15/10/2021	21/10/2021	28/10/2021
02/09/2021	14/10/2021	04/11/2021	12/11/2021	19/11/2021	25/11/2021	02/12/2021
30/09/2021	25/11/2021	16/12/2021	21/12/2021	31/12/2021	06/01/2022	13/01/2022

<sup>1</sup> Timetable for Art. 107i referral can be found here: [https://www.ema.europa.eu/documents/other/timetable-safety-referral-artide-107i-urgent-union-procedure\\_en.pdf](https://www.ema.europa.eu/documents/other/timetable-safety-referral-artide-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
28/11/2021	23/12/2021	13/01/2022	21/01/2022	28/01/2022	03/02/2022	10/02/2022
02/12/2021	20/01/2022	10/02/2022	18/02/2022	25/02/2022	03/03/2022	10/03/2022
13/01/2022	17/02/2022	10/03/2022	18/03/2022	25/03/2022	31/03/2022	07/04/2022
10/02/2022	17/03/2022	07/04/2022	13/04/2022	22/04/2022	28/04/2022	05/05/2022
10/03/2022	22/04/2022	13/05/2022	19/05/2022	25/05/2022	03/06/2022	10/06/2022
07/04/2022	19/05/2022	09/06/2022	17/06/2022	24/06/2022	30/06/2022	07/07/2022
05/05/2022	16/06/2022	07/07/2022	15/07/2022	22/07/2022	28/07/2022	04/08/2022***
10/06/2022	14/07/2022	04/08/2022	12/08/2022	19/08/2022	25/08/2022	01/09/2022
07/07/2022	11/08/2022	01/09/2022	09/09/2022	16/09/2022	22/09/2022	29/09/2022
04/08/2022***	08/09/2022	29/09/2022	07/10/2022	14/10/2022	20/10/2022	27/10/2022
01/09/2022	13/10/2022	03/11/2022	11/11/2022	18/11/2022	24/11/2022	01/12/2022
29/09/2022	24/11/2022	15/12/2022	23/12/2022	30/12/2022	05/01/2023	12/01/2023
27/10/2022	22/12/2022	12/01/2023	20/01/2023	27/01/2023	02/02/2023	09/02/2023
01/12/2022	26/01/2023	16/02/2023	24/02/2023	03/03/2023	09/03/2023	16/03/2023
12/01/2023	24/02/2023	17/03/2023	24/03/2023	31/03/2023	05/04/2023	14/04/2023
09/02/2023	24/03/2023	14/04/2023	21/04/2023	28/04/2023	05/05/2023	12/05/2023
16/03/2023	20/04/2023	11/05/2023	17/05/2023	26/05/2023	01/06/2023	08/06/2023
14/04/2023	18/05/2023	08/06/2023	16/06/2023	23/06/2023	29/06/2023	06/07/2023
12/05/2023	15/06/2023	06/07/2023	14/07/2023	21/07/2023	27/07/2023	03/08/2023***
08/06/2023	13/07/2023	03/08/2023	11/08/2023	18/08/2023	24/08/2023	31/08/2023
06/07/2023	10/08/2023	31/08/2023	08/09/2023	15/09/2023	21/09/2023	28/09/2023
03/08/2023***	07/09/2023	28/09/2023	06/10/2023	13/10/2023	19/10/2023	26/10/2023
31/08/2023	12/10/2023	02/11/2023	10/11/2023	17/11/2023	23/11/2023	30/11/2023
28/09/2023	23/11/2023	14/12/2023	22/12/2023	29/12/2023	04/01/2024	11/01/2024
26/10/2023	21/12/2023	11/01/2024	19/01/2024	26/01/2024	01/02/2024	08/02/2024
30/11/2023	18/01/2024	08/02/2024	16/02/2024	23/02/2024	29/02/2024	07/03/2024

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

## 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
10/06/2021	17/06/2021	08/07/2021	16/07/2021	23/07/2021	29/07/2021	05/08/2021***
08/07/2021	15/07/2021	05/08/2021	13/08/2021	20/08/2021	26/08/2021	02/09/2021
05/08/2021***	12/08/2021	02/09/2021	10/09/2021	17/09/2021	23/09/2021	30/09/2021
02/09/2021	09/09/2021	30/09/2021	08/10/2021	15/10/2021	21/11/2021	28/10/2021
30/09/2021	14/10/2021	04/11/2021	12/11/2021	19/11/2021	25/11/2021	02/12/2021
28/10/2021	25/11/2021	16/12/2021	21/12/2021	31/12/2021	06/01/2022	13/01/2022
02/12/2021	23/12/2021	13/01/2022	21/01/2022	28/01/2022	03/02/2022	10/02/2022
13/01/2022	20/01/2022	10/02/2022	18/02/2022	25/02/2022	03/03/2022	10/03/2022

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
10/02/2022	17/02/2022	10/03/2022	18/03/2022	25/03/2022	31/03/2022	07/04/2022
10/03/2022	17/03/2022	07/04/2022	13/04/2022	22/04/2022	28/04/2022	05/05/2022
07/04/2022	22/04/2022	13/05/2022	17/05/2022	26/05/2022	02/06/2022	10/06/2022
05/05/2022	19/05/2022	09/06/2022	17/06/2022	24/06/2022	30/06/2022	07/07/2022
10/06/2022	16/06/2022	07/07/2022	15/07/2022	22/07/2022	28/07/2022	04/08/2022***
07/07/2022	14/07/2022	04/08/2022	12/08/2022	19/08/2022	25/08/2022	01/09/2022
04/08/2022***	11/08/2022	01/09/2022	09/09/2022	16/09/2022	22/09/2022	29/09/2022
01/09/2022	08/09/2022	29/09/2022	07/10/2022	14/10/2022	20/10/2022	27/10/2022
29/09/2022	13/10/2022	03/11/2022	11/11/2022	18/11/2022	24/11/2022	01/12/2022
27/10/2022	24/11/2022	15/12/2022	23/12/2022	30/12/2022	05/01/2023	12/01/2023
01/12/2022	22/12/2022	12/01/2023	20/01/2023	27/01/2023	02/02/2023	09/02/2023
12/01/2023	26/01/2023	16/02/2023	24/02/2023	03/03/2023	09/03/2023	16/03/2023
09/02/2023	24/02/2023	17/03/2023	24/03/2023	31/03/2023	05/04/2023	14/04/2023
16/03/2023	24/03/2023	14/04/2023	21/04/2023	28/04/2023	05/05/2023	12/05/2023
14/04/2023	20/04/2023	11/05/2023	17/05/2023	26/05/2023	01/06/2023	08/06/2023
12/05/2023	18/05/2023	08/06/2023	16/06/2023	23/06/2023	29/06/2023	06/07/2023
08/06/2023	15/06/2023	06/07/2023	14/07/2023	21/07/2023	27/07/2023	03/08/2023***
06/07/2023	13/07/2023	03/08/2023	11/08/2023	18/08/2023	24/08/2023	31/08/2023
03/08/2023***	10/08/2023	31/08/2023	08/09/2023	15/09/2023	21/09/2023	28/09/2023
31/08/2023	07/09/2023	28/09/2023	06/10/2023	13/10/2023	19/10/2023	26/10/2023
28/09/2023	12/10/2023	02/11/2023	10/11/2023	17/11/2023	23/11/2023	30/11/2023
26/10/2023	23/11/2023	14/12/2023	22/12/2023	29/12/2023	04/01/2024	11/01/2024
30/11/2023	21/12/2023	11/01/2024	19/01/2024	26/01/2024	01/02/2024	08/02/2024
11/01/2024	18/01/2024	08/02/2024	16/02/2024	23/02/2024	29/02/2024	07/03/2024
08/02/2024	22/02/2024	14/03/2024	22/03/2024	27/03/2024	04/04/2024	11/04/2024
07/03/2024	28/03/2024	18/04/2024	26/04/2024	03/05/2024	08/05/2024	16/05/2024

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	25/04/2024	16/05/2024	24/05/2024	31/05/2024	06/06/2024	13/06/2024
16/05/2024	23/05/2024	13/06/2024	21/06/2024	28/06/2024	04/07/2024	11/07/2024
13/06/2024	20/06/2024	11/07/2024	19/07/2024	26/07/2024	01/08/2024	08/08/2024***
11/07/2024	18/07/2024	08/08/2024	16/08/2024	23/08/2024	29/08/2024	05/09/2024
08/08/2024***	15/08/2024	05/09/2024	13/09/2024	20/09/2024	26/09/2024	03/10/2024
05/09/2024	12/09/2024	03/10/2024	11/10/2024	18/10/2024	24/10/2024	31/10/2024
03/10/2024	10/10/2024	31/10/2024	08/11/2024	15/11/2024	21/11/2024	28/11/2024

### 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
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***	11/08/2021	16/08/2021	20/08/2021	25/08/2021	27/08/2021	02/09/2021
02/09/2021	08/09/2021	13/09/2021	17/09/2021	22/09/2021	24/09/2021	30/09/2021
30/09/2021	06/10/2021	11/10/2021	15/10/2021	20/10/2021	22/10/2021	28/10/2021
28/10/2021	10/11/2021	15/11/2021	19/11/2021	24/11/2021	26/11/2021	02/12/2021
02/12/2021	22/12/2021	27/12/2021	03/01/2022	05/01/2022	07/01/2022	13/01/2022
13/01/2022	19/01/2022	24/01/2022	28/01/2022	02/02/2022	04/02/2022	10/02/2022
10/02/2022	16/02/2022	21/02/2022	25/02/2022	02/03/2022	04/03/2022	10/03/2022
10/03/2022	16/03/2022	21/03/2022	25/03/2022	30/03/2022	01/04/2022	07/04/2022
07/04/2022	13/04/2022	18/04/2022	22/04/2022	27/04/2022	29/04/2022	05/05/2022

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
05/05/2022	19/05/2022	24/05/2022	25/05/2022	01/06/2022	03/06/2022	10/06/2022
10/06/2022	15/06/2022	20/06/2022	24/06/2022	29/06/2022	01/07/2022	07/07/2022
07/07/2022	13/07/2022	18/07/2022	22/07/2022	27/07/2022	29/07/2022	04/08/2022***
04/08/2022***	10/08/2022	15/08/2022	19/08/2022	24/08/2022	26/08/2022	01/09/2022
01/09/2022	07/09/2022	12/09/2022	16/09/2022	21/09/2022	23/09/2022	29/09/2022
29/09/2022	05/10/2022	10/10/2022	14/10/2022	19/10/2022	21/10/2022	27/10/2022
27/10/2022	09/11/2022	14/11/2022	18/11/2022	23/11/2022	25/11/2022	01/12/2022
01/12/2022	21/12/2022	26/12/2022	02/01/2023	04/01/2023	06/01/2023	12/01/2023
12/01/2023	18/01/2023	23/01/2023	27/01/2023	01/02/2023	03/02/2023	09/02/2023
09/02/2023	22/02/2023	27/02/2023	03/03/2023	08/03/2023	10/03/2023	16/03/2023
16/03/2023	23/03/2023	28/03/2023	29/03/2023	03/04/2023	05/04/2023	14/04/2023
14/04/2023	20/04/2023	25/04/2023	28/04/2023	04/05/2023	05/05/2023	12/05/2023
12/05/2023	17/05/2023	22/05/2023	26/05/2023	31/05/2023	02/06/2023	08/06/2023
08/06/2023	14/06/2023	19/06/2023	23/06/2023	28/06/2023	30/06/2023	06/07/2023
06/07/2023	12/07/2023	17/07/2023	21/07/2023	26/07/2023	28/07/2023	03/08/2023***
03/08/2023***	09/08/2023	14/08/2023	18/08/2023	23/08/2023	25/08/2023	31/08/2023
31/08/2023	06/09/2023	11/09/2023	15/09/2023	20/09/2023	22/09/2023	28/09/2023
28/09/2023	04/10/2023	09/10/2023	13/10/2023	18/10/2023	20/10/2023	26/10/2023
26/10/2023	08/11/2023	13/11/2023	17/11/2023	22/11/2023	24/11/2023	30/11/2023
30/11/2023	10/12/2023	24/12/2023	29/12/2024	03/01/2024	05/01/2024	11/01/2024
11/01/2024	17/01/2024	22/01/2024	26/01/2024	31/01/2024	02/02/2024	08/02/2024
08/02/2024	14/02/2024	19/02/2024	23/02/2024	28/02/2024	01/03/2024	07/03/2024
07/03/2024	20/03/2024	25/03/2024	27/03/2024	03/04/2024	05/04/2024	11/04/2024
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	31/05/2024	05/06/2024	07/06/2024	13/06/2024
13/06/2024	19/06/2024	24/06/2024	28/06/2024	03/07/2024	05/07/2024	11/07/2024

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
11/07/2024	17/07/2024	22/07/2024	26/07/2024	31/07/2024	02/08/2024	08/08/2024***
08/08/2024***	14/08/2024	19/08/2024	23/08/2024	28/08/2024	30/08/2024	05/09/2024
05/09/2024	11/09/2024	16/09/2024	20/09/2024	25/09/2024	27/09/2024	03/10/2024
03/10/2024	09/10/2024	14/10/2024	18/10/2024	23/10/2024	25/10/2024	31/10/2024
31/10/2024	06/11/2024	11/11/2024	15/11/2024	20/11/2024	22/11/2024	28/11/2024

.(\*)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)

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