



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