



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 September 2023
EMA/273042/2023
Human Medicines Division

Timetable Safety referrals (Art 107i, urgent Union procedure)

Submission date(*)	Start date	PRAC (Co) Rapporteur Preliminary Assessment Report	Comments from PRAC & CHMP/CMDh members (**)	PRAC (Co) Rapporteur final Assessment Report	PRAC Recommendation	CHMP Opinion / CMDh position
24/07/2023	31/07/2023	24/08/2023	12/09/2023	18/09/2023	28/09/2023	12/10/2023
21/08/2023	28/08/2023	21/09/2023	10/10/2023	16/10/2023	26/10/2023	09/11/2023
25/09/2023	02/10/2023	26/10/2023	14/11/2023	20/11/2023	30/11/2023	14/12/2023
06/11/2023	13/11/2023	07/12/2023	28/12/2023	03/01/2024	11/01/2024	25/01/2024
04/12/2023	11/12/2023	04/01/2024	23/01/2024	29/01/2024	08/02/2024	22/02/2024
02/01/2024	08/01/2024	01/02/2024	20/02/2024	26/02/2024	07/03/2024	21/03/2024
05/02/2024	12/02/2024	07/03/2024	26/03/2024	02/04/2024	11/04/2024	25/04/2024
11/03/2024	18/03/2024	11/04/2024	30/04/2024	06/05/2024	16/05/2024	30/05/2024
08/04/2024	15/04/2024	08/05/2024	28/05/2024	03/06/2024	13/06/2024	27/06/2024

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An agency of the European Union



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

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29/06/2026	06/07/2026	30/07/2026	18/08/2026	24/08/2026	03/09/2026	17/09/2026
27/07/2026	03/08/2026	27/08/2026	15/09/2026	21/09/2026	01/10/2026	15/10/2026
24/08/2026	31/08/2026	24/09/2026	13/10/2026	19/10/2026	29/10/2026	12/11/2026
21/09/2026	28/09/2026	22/10/2026	10/11/2026	16/11/2026	26/11/2026	10/12/2026

(*) 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 PRAC/CMDh/CHMP members are not made available to marketing authorisation holders at that stage

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