



13 July 2021
EMA/36438/2021
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
28/06/2021	05/07/2021	30/07/2021	17/08/2021	23/08/2021	02/09/2021	16/09/2021
26/07/2021	02/08/2021	27/08/2021	14/09/2021	20/09/2021	30/09/2021	14/10/2021
23/08/2021	30/08/2021	24/09/2021	12/10/2021	18/10/2021	28/10/2021	11/11/2021
27/09/2021	04/10/2021	29/10/2021	16/11/2021	22/11/2021	02/12/2021	16/12/2021
08/11/2021	15/11/2021	10/12/2021	28/12/2021	03/01/2022	13/01/2022	27/01/2022
06/12/2021	13/12/2021	07/01/2022	25/01/2022	31/01/2022	10/02/2022	24/02/2022
03/01/2022	10/01/2022	04/02/2022	22/02/2022	28/02/2022	10/03/2022	24/03/2022
31/01/2022	07/02/2022	04/03/2022	22/03/2022	28/03/2022	07/04/2022	22/04/2022
28/02/2022	07/03/2022	01/04/2022	19/04/2022	25/04/2022	05/05/2022	19/05/2022

Official address Domenico Scarlattilaan 6 • 1083 HS Amsterdam • The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
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An agency of the European Union



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

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

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