



12 February 2026
EMA/397812/2025

Human Medicines Division

The timetables in this document may be subject to revision

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

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24/08/2026	31/08/2026	24/09/2026	12/10/2026	20/10/2026	29/10/2026	12/11/2026
21/09/2026	28/09/2026	22/10/2026	09/11/2026	17/11/2026	26/11/2026	10/12/2026
09/11/2026	16/11/2026	10/12/2026	28/12/2026	05/01/2027	14/01/2027	28/01/2027
07/12/2026	14/12/2026	07/01/2027	25/01/2027	02/02/2027	11/02/2027	25/02/2027
11/01/2027	18/01/2027	11/02/2027	01/03/2027	09/03/2027	18/03/2027	02/04/2027
08/02/2027	15/02/2027	11/03/2027	30/03/2027	06/04/2027	15/04/2027	30/04/2027
08/03/2027	15/03/2027	08/04/2027	26/04/2027	04/05/2027	13/05/2027	27/05/2027
05/04/2027	12/04/2027	05/05/2027	24/05/2027	01/06/2027	10/06/2027	24/06/2027
03/05/2027	10/05/2027	03/06/2027	21/06/2027	29/06/2027	08/07/2027	22/07/2027
31/05/2027	07/06/2027	01/07/2027	19/07/2027	27/07/2027	05/08/2027***	19/08/2027***
28/06/2027	05/07/2027	29/07/2027	16/08/2027	24/08/2027	02/09/2027	16/09/2027
26/07/2027	02/08/2027	26/08/2027	13/09/2027	21/09/2027	30/09/2027	14/10/2027
23/08/2027	30/08/2027	23/09/2027	11/10/2027	19/10/2027	28/10/2027	11/11/2027
27/09/2027	04/10/2027	28/10/2027	15/11/2027	23/11/2027	02/12/2027	16/12/2027
08/11/2027	15/11/2027	09/12/2027	27/12/2027	04/01/2028	13/01/2028	27/01/2028
06/12/2027	13/12/2027	06/01/2028	24/01/2028	01/02/2028	10/02/2028	24/02/2028
03/01/2028	10/01/2028	03/02/2028	21/02/2028	29/02/2028	09/03/2028	23/03/2028
31/01/2028	07/02/2028	02/03/2028	20/03/2028	28/03/2028	06/04/2028	21/04/2028
29/02/2028	07/03/2028	31/03/2028	18/04/2028	26/04/2028	05/05/2028	18/05/2028
04/04/2028	11/04/2028	05/05/2028	23/05/2028	31/05/2028	09/06/2028	22/06/2028
02/05/2028	08/05/2028	01/06/2028	19/06/2028	27/06/2028	06/07/2028	20/07/2028
30/05/2028	06/06/2028	30/06/2028	18/07/2028	26/07/2028	03/08/2028***	17/08/2028***
26/06/2028	03/07/2028	27/07/2028	14/08/2028	22/08/2028	31/08/2028	14/09/2028
24/07/2028	31/07/2028	24/08/2028	11/09/2028	19/09/2028	28/09/2028	12/10/2028

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25/09/2028	02/10/2028	26/10/2028	13/11/2028	21/11/2028	30/11/2028	14/12/2028

(*) 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 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