



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

5 February 2025
EMADOC-628903358-40450
Human Medicines - Scientific Evidence Generation

Deadlines for submission of applications for orphan medicinal product designation to the EMA and corresponding COMP timetable for valid applications 2025/2026

Submission deadline	Start of procedure Day 1	COMP meeting Day 60 (1 st discussion)	COMP meeting* Day 90 (2 nd discussion)
27 January 2025	26 February 2025	14-16 April 2025	13-15 May 2025
27 February 2025	25 March 2025	13-15 May 2025	10-12 June 2025
27 March 2025	22 April 2025	10-12 June 2025	15-17 July 2025
26 May 2025	17 June 2025	15-17 July 2025	9-11 September 2025
26 June 2025	15 July 2025	9-11 September 2025	7-9 October 2025
15 July 2025	15 August 2025	7-9 October 2025	4-6 November 2025
29 August 2025	15 Sept 2025	4-6 November 2025	2-4 December 2025
30 September 2025	28 October 2025	2-4 December 2025	20-22 January 2026
28 October 2025	24 November 2025	20-22 January 2026	17-19 February 2026
25 November 2025	5 January 2026	17-19 February 2026	17-19 March 2026
12 December 2025	26 January 2026	17-19 March 2026	14-16 April 2026
27 January 2026	26 February 2026	14-16 April 2026	11-13 May 2026
27 February 2026	25 March 2026	11-13 May 2026	16-18 June 2026
27 March 2026	22 April 2026	16-18 June 2026	14-16 July 2026
26 May 2026	17 June 2026	14-16 July 2026	8-10 September 2026
26 June 2026	15 July 2026	8-10 September 2026	6-8 October 2026
14 July 2026	14 August 2026	6-8 October 2026	3-5 November 2026
28 August 2026	14 September 2026	3-5 November 2026	1-3 December 2026

* Committee for Orphan Medicinal Products

Note: In accordance with Article 5.5 of Regulation (EC) No 141/2000, the COMP will reach an opinion on a valid application for orphan designation within 90 days. Opinions may be reached earlier than day 90 if no questions are raised by COMP. In preparing an application for orphan designation, sponsors are requested to follow the Commission guideline (ENTR/6283/00) for the format and content of applications for designation as orphan medicinal products, available on the EMA corporate web-site.

