



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 March 2024
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 2024/2025

Submission deadline	Start of procedure Day 1	COMP meeting Day 60 (1 st discussion)	COMP meeting* Day 90 (2 nd discussion)
27/03/2024	22 April 2024	18-20 June 2024	16-18 July 2024
22/05/2024	17 June 2024	16-18 July 2024	10-12 September 2024
24/06/2024	15 July 2024	10-12 September 2024	8-10 October 2024
15/07/2024	15 August 2024	8-10 October 2024	5-7 November 2024
30/08/2024	13 September 2024	5-7 November 2024	3-5 December 2024
30/09/2024	26 October 2024	3-5 December 2024	21-23 January 2025
28/10/2024	23 November 2024	21-23 January 2025	18-20 February 2025
25/11/2024	4 January 2025	18-20 February 2025	18-20 March 2025
16/12/2024	26 January 2025	18-20 March 2025	14-16 April 2025
27/01/2025	26 February 2025	14-16 April 2025	13-15 May 2025
27/02/2025	25 March 2025	13-15 May 2025	10-12 June 2025
27/03/2025	22 April 2025	10-12 June 2025	15-17 July 2025
26/05/2025	17 June 2025	15-17 July 2025	9-11 September 2025
26/06/2025	15 July 2025	9-11 September 2025	7-9 October 2025
15/07/2025	15 August 2025	7-9 October 2025	4-6 November 2025
29/08/2025	13 Sept 2025	4-6 November 2025	2-4 December 2025

* 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.

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

Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

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