



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

16 January 2026  
EMADOC-628903358-133247  
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 2026/2027

Submission deadline	Start of procedure Day 1	COMP meeting Day 60 (1 <sup>st</sup> discussion)	COMP meeting* Day 90 (2 <sup>nd</sup> discussion)
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
30 September 2026	28 October 2026	1-3 December 2026	19-21 January 2027
29 October 2026	24 November 2026	19-21 January 2027	16-18 February 2027
24 November 2026	5 January 2027	16-18 February 2027	22-24 March 2027
11 December 2026	28 January 2027	22-24 March 2027	20-22 April 2027
29 January 2027	26 February 2027	20-22 April 2027	18-20 May 2027
26 February 2027	23 March 2027	18-20 May 2027	15-17 June 2027
31 March 2027	26 April 2027	15-17 June 2027	13-15 July 2027
27 May 2027	18 June 2027	13-15 July 2027	7-9 September 2027
28 June 2027	16 July 2027	7-9 September 2027	5-7 October 2027
14 July 2027	13 August 2027	5-7 October 2027	3-5 November 2027
31 August 2027	15 September 2027	3-5 November 2027	7-9 December 2027

\* 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](http://www.ema.europa.eu/how-to-find-us)

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

An agency of the European Union



© European Medicines Agency, 2026. Reproduction is authorised provided the source is acknowledged.