



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 July 2018
EMA/171388/2018
Human Medicines Research and Development Support Division

Deadlines for submission of applications for orphan medicinal product designation to the EMA and corresponding COMP timetable for valid applications 2018/2019

Submission deadline	Start of procedure Day 1	COMP meeting Day 60 (1 st discussion)	COMP meeting* Day 90 (2 nd discussion)
23 March 2018	23 April 2018	19-21 June 2018	17-19 July 2018
24 May 2018	18 June 2018	17-19 July 2018	11-13 September 2018
29 June 2018	16 July 2018	11-13 September 2018	9-11 October 2018
17 July 2018	13 August 2018	9-11 October 2018	6-8 November 2018
30 August 2018	12 September 2018	6-8 November 2018	4-6 December 2018
27 September 2018	29 October 2018	4-6 December 2018	22-24 January 2019
25 October 2018	26 November 2018	22-24 January 2019	19-21 February 2019
22 November 2018	3 January 2019	19-21 February 2019	19-21 March 2019
6 December 2018	18 January 2019	19-21 March 2019	15-17 April 2019
24 January 2019	25 February 2019	15-17 April 2019	21-23 May 2019
28 February 2019	25 March 2019	21-23 May 2019	18-20 June 2019
21 March 2019	23 April 2019	18-20 June 2019	16-18 July 2019
23 May 2019	17 June 2019	16-18 July 2019	10-12 September 2019
27 June 2019	15 July 2019	10-12 September 2019	8-10 October 2019
17 July 2019	12 August 2019	8-10 October 2019	5-7 November 2019
28 August 2019	13 September 2019	5-7 November 2019	3-5 December 2019

* 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.

