



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

23 March 2017
EMA/203314/2017
Human Medicines Research and Development Support Division

Deadlines for submission of applications for orphan medicinal product designation to the EMA 2017/2018

Deadline for submission of applications	Start of procedure - day 1 (for validated applications)	COMP* meeting (see note below)
22 May 2017	12 June 2017	5-7 September 2017
26 June 2017	14 July 2017	3-5 October 2017
17 July 2017	3 August 2017	30-31 October 2017
31 August 2017	18 September 2017	5-7 December 2017
28 September 2017	23 October 2017	16-18 January 2018
26 October 2017	20 November 2017	13-15 February 2018
23 November 2017	18 December 2017	13-15 March 2018
7 December 2017	22 January 2018	17-19 April 2018
25 January 2018	26 February 2018	22-24 May 2018
27 February 2018	26 March 2018	19-21 June 2018
23 March 2018	23 April 2018	17-19 July 2018
24 May 2018	18 June 2018	11-13 September 2018
29 June 2018	16 July 2018	09-11 October 2018
17 July 2018	13 August 2018	6-8 November 2018
30 August 2018	12 September 2018	4-6 December 2018

* 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. Please note that the dates provided above correspond to the COMP meeting falling on or just prior to day 90. 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 web-site.

