25 April 2022
EMADOC-628903358-2283
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

2022/2023

Submission deadline	Start of procedure Day 1	COMP meeting Day 60 (1st discussion)	COMP meeting* Day 90 (2nd discussion)
20/05/2022	14 June 2022	12-14 July 2022	6-8 September 2022
24/06/2022	12 July 2022	6-8 September 2022	4-6 October 2022
15/07/2022	15 August 2022	4-6 October 2022	8-10 November 2022
31/08/2022	14 September 2022	8-10 November 2022	6-8 December 2022
28/09/2022	26 October 2022	6-8 December 2022	17-19 January 2023
26/10/2022	23 November 2022	17-19 January 2023	14-16 February 2023
24/11/2022	4 January 2023	14-16 February 2023	21-23 March 2023
6/12/2022	25 January 2023	21-23 March 2023	18-20 April 2023
26/01/2023	20 February 2023	18-20 April 2023	15-17 May 2023
27/02/2023	22 March 2023	15-17 May 2023	13-15 June 2023
27/03/2023	19 April 2023	13-15 June 2023	11-13 July 2023
22/05/2023	13 June 2023	11-13 July 2023	5-7 September 2023
23/06/2023	11 July 2023	5-7 September 2023	3-5 October 2023
14/07/2023	15 August 2023	3-5 October 2023	7-9 November 2023
29/08/2023	14 September 2023	7-9 November 2023	5-7 December 2023

* 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.

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