



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 December 2019
EMA/CHMP/848532/2018 Rev. 5

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

Fosfomycin-containing medicinal products

Procedure no: EMEA/H/A-31/1476

Procedural step:	Date
Notification:	07 December 2018
Start of the procedure (CHMP):	December 2018 CHMP
List of questions:	13 December 2018
Submission of responses:	07 February 2019
Re-start of the procedure:	28 February 2019
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	08 March 2019
Comments:	15 March 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	21 March 2019
CHMP list of outstanding issues:	28 March 2019
Submission of responses:	09 May 2019
Re-start of the procedure:	30 May 2019
Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	07 June 2019
Comments:	14 June 2019

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Procedural step:	Date
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to CHMP:	20 June 2019
2 nd CHMP list of outstanding issues:	27 June 2019
Consultation with the Infectious Disease Working Party (IDWP)	17 July 2019
Submission of responses:	1 August 2019
Re-start of the procedure:	22 August 2019
Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	30 August 2019
Comments:	6 September 2019
Updated Rapporteur/co-rapporteur assessment report(s) circulated to CHMP:	12 September 2019
3 rd CHMP list of outstanding issues:	19 September 2019
Submission of responses:	24 October 2019
Re-start of the procedure:	14 November 2019
Joint Assessment report circulated to CHMP:	22 November 2019
Comments:	29 November 2019
Updated joint assessment report circulated to CHMP:	5 December 2019
Oral explanation	10 December 2019
4 th CHMP list of outstanding issues:	12 December 2019
Submission of responses:	6 February 2020
Re-start of the procedure:	27 February 2020
Joint Assessment report circulated to CHMP:	6 March 2020
Comments:	13 March 2020
Updated joint assessment report circulated to CHMP:	19 March 2020
CHMP opinion:	March 2020 CHMP