



3 December 2015
EMA/PRAC/550970/2015 rev1.

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC resulting from
pharmacovigilance data

Fusafungine containing medicinal products for oromucosal and nasal use

Procedure no: EMEA/H/A-31/1420

Procedural step:	Date
Notification:	06 August 2015
Start of the procedure (PRAC):	September, 2015 PRAC
List of questions:	10 September 2015
Submission of responses:	22 October 2015
Re-start of the procedure:	05 November 2015
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh ¹ :	18 November 2015
Comments:	23 November 2015
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CMDh	26 November 2015
PRAC list of outstanding issues:	December 2015 PRAC
Submission of responses:	31 December 2015
Re-start of the procedure:	14 January 2016

¹ Coordination Group for Mutual Recognition & Decentralised Procedures - Human



Procedural step:	Date
Scientific Advisory Group (SAG):	21 January 2016
Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	27 January 2016
Comments:	1 February 2016
Updated Rapporteur/co-rapporteur joint assessment report circulated to PRAC and to CMDh:	4 February 2016
PRAC recommendation:	February 2016 PRAC