



21 July 2016
EMA/CHMP/428619/2016 Rev.1

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

To be addressed by the marketing authorisation holders of medicinal products for which Pharmaceuticals International Inc, Maryland, USA, is included in the marketing authorisation as manufacturing site.

Procedure no: EMEA/H/A-31/1444

Ammonaps EMEA/H/C/000219/A31/0048

Procedural step:	Date
Notification:	17 June 2016
Start of the procedure (CHMP):	June 2016 CHMP meeting
List of questions:	23 June 2016
Submission of responses:	01 July 2016
Re-start of the procedure:	04 July 2016
Rapporteur/co-rapporteur assessment reports circulated to CHMP:	08 July 2016
Comments:	13 July 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	15 July 2016
CHMP list of outstanding issues or CHMP opinion:	July 2016 CHMP meeting
Submission of responses:	10 August 2016



Procedural step:	Date
Re-start of the procedure:	18 August 2016
Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	31 August 2016
Comments:	05 September 2016
Updated Rapporteur/co-rapporteur joint assessment report circulated to CHMP:	08 September 2016
CHMP list of outstanding issues or CHMP opinion:	September 2016 CHMP meeting