



15 December 2016  
EMA/CHMP/147246/2016 Rev. 4

## Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

Dienogest/ethinylestradiol containing medicinal products

Procedure no: EMEA/H/A-31/1435

<b>Procedural step:</b>	<b>Date</b>
Notification:	18 February 2016
Start of the procedure (CHMP):	February, 2016 CHMP
List of questions:	25 February 2016
Submission of responses:	14 April 2016
Re-start of the procedure:	28 April 2016
Rapporteur/co-rapporteur assessment reports circulated to CHMP:	8 June 2016
Comments:	13 June 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	16 June 2016
CHMP list of outstanding issues:	June 2016 CHMP
Submission of responses:	4 August 2016
Re-start of the procedure:	18 August 2016



<b>Procedural step:</b>	<b>Date</b>
Rapporteur/co-rapporteur joint assessment reports circulated to CHMP:	31 August 2016
Comments:	5 September 2016
Updated Rapporteur/co-rapporteur joint assessment reports circulated to CHMP:	8 September 2016
CHMP list of outstanding issues:	20 September, 2016 CHMP
Submission of responses:	08 November 2016
Re-start of the procedure:	22 November 2016
Rapporteur/co-rapporteur joint assessment reports circulated to CHMP:	30 November 2016
Comments:	05 December 2016
Updated Rapporteur/co-rapporteur joint assessment reports circulated to CHMP:	08 December 2016
CHMP list of outstanding issues:	15 December, 2016 CHMP
Submission of responses:	04 January 2017
Re-start of the procedure:	09 January 2017
Rapporteur/co-rapporteur joint assessment reports circulated to CHMP:	13 January 2017
Comments:	18 January 2017
Updated Rapporteur/co-rapporteur joint assessment reports circulated to CHMP:	20 January 2017
CHMP Opinion	26 January 2017