EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

11 July 2013
EMA/PRAC/122032/2013 - Rev 4

Timetable for the procedure

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

Procedure no: Combined hormonal contraceptives EMEA/H/A-31/1356 (INN: chlormadinone, desogestrel, dienogest, drospirenone, etonogestrel, gestodene, nomegestrol, norelgestromin or norgestimate) containing medicinal products

Zoely EMEA/H/A-31/1356/C/1213/0010
Ioa EMEA/H/A-31/1356/C/2068/0007
Evra EMEA/H/A-31/1356/C/410/0031

Procedural step:	**Date**
Notification:	22 January 2013
Start of the procedure (PRAC):	February 2013 PRAC
List of questions:	07 February 2013
Submission of responses:	08 April 2013
Restart	15 April 2013
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CHMP[1]:	27 June 2013
Ad hoc expert meeting	02 July 2013
Comments:	03 July 2013
Updated Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CHMP:	05 July 2013
PRAC list of outstanding issues	July 2013 PRAC
Submission of responses:	3 September 2013

[1] Committee for Medicinal Products for Human Use

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Procedural step:	**Date**
Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CHMP:	23 September 2013
Comments:	30 September 2013
Updated Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and to CHMP:	3 October 2013
Oral explanations / PRAC recommendation to CHMP:	October 2013 PRAC