12 July 2018
EMA/PRAC/38618/2017 Rev. 6

Timetable for the procedure

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

Quinolone and fluoroquinolone containing medicinal products

Procedure no: EMEA/H/A-31/1452

Quinsair EMEA/H/A-31/1452/C/002789/0010

Procedural step:	**Date**
Notification:	01 February 2017
Start of the procedure (PRAC):	February 2017 PRAC
List of questions:	09 February 2017
Submission of responses:	07 August 2017
Re-start of the procedure:	31 August 2017
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]:	08 September 2017
Comments:	15 September 2017
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	21 September 2017
PRAC list of outstanding issues:	06 October 2017
Submission of responses:	28 December 2017

[1] Committee for Medicinal Products for Human Use

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Procedural step:	**Date**
Re-start of the procedure:	11 January 2018
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	24 January 2018
Comments:	29 January 2018
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP	01 February 2018
2nd PRAC list of outstanding issues:	08 February 2018
Submission of responses:	31 May 2018
Re-start of the procedure:	14 June 2018
Public Hearing:	13 June 2018
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	25 June 2018
Comments:	02 July 2018
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	05 July 2018
3rd PRAC list of outstanding issues:	12 July 2018
Submission of responses:	23 August 2018
Re-start of the procedure:	6 September 2018
Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	13 September 2018
Comments:	24 September 2018
Updated Rapporteur/co-rapporteur joint assessment report(s) circulated to PRAC and to CHMP:	27 September 2018
PRAC recommendation:	October, 2018 PRAC