10 December 2019
EMA/PRAC/165647/2019 Rev. 4

Timetable for the procedure

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

Fluorouracil and fluorouracil related substances (capecitabine, tegafur and flucytosine) containing medicinal products

Procedure number: EMEA/H/A-31/1481

Xeloda EMEA/H/A-31/1481/C/000316/0085

Teysuno EMEA/H/A-31/1481/C/001242/0040

Capecitabine Accord EMEA/H/A-31/1481/C/002386/0032

Capecitabine Medac EMEA/H/A-31/1481/C/002568/0021

Capecitabine Teva EMEA/H/A-31/1481/C/002362/0031

Ecansya EMEA/H/A-31/1481/C/002605/0023

Procedural step:	**Date**
Notification:	06 March 2019
Start of the procedure (PRAC):	March, 2019 PRAC
List of questions:	15 March 2019
Submission of responses:	20 May 2019
Re-start of the procedure:	13 June 2019

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Procedural step:	**Date**
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]:	21 June 2019
Comments:	28 June 2019
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	4 July 2019
PRAC list of outstanding issues:	July, 2019 PRAC
Submission of responses:	10 October 2019
Scientific Advisory Group on Oncology:	11 October 2019
Re-start of the procedure:	31 October 2019
Rapporteurs joint assessment report circulated to PRAC and to CHMP:	8 November 2019
Comments:	15 November 2019
Rapporteurs joint updated assessment report circulated to PRAC and to CHMP:	21 November 2019
PRAC list of outstanding issues:	December, 2019 PRAC
Submission of responses:	23 January 2020
Re-start of the procedure:	13 February 2020
Rapporteurs joint assessment report circulated to PRAC and to CHMP:	21 February 2020
Comments:	28 February 2020
Rapporteurs joint updated assessment report circulated to PRAC and to CHMP:	5 March 2020
PRAC list of outstanding issues or PRAC recommendation:	12 March 2020

[1] Committee for Medicinal Products for Human Use