14 June 2018
EMA/PRAC/791811/2017 Rev. 2

Timetable for the procedure

Article 20 of Regulation (EC) No 726/2004 resulting from pharmacovigilance data

Xofigo

Procedure number: EMEA/H/A-20/1459/C/002653/0028

Procedural step:	**Date**
Notification:	30 November 2017
Start of the procedure (PRAC):	December, 2017 PRAC (27-30 November 2017)
List of questions:	30 November 2017
Submission of responses:	12 January 2018
Re-start of the procedure:	08 February 2018
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]:	21 February 2018
Comments:	27 February 2018
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	01 March 2018
PRAC list of outstanding issues:	March, 2018 PRAC
Submission of responses:	03 May 2018
Re-start of the procedure:	17 May 2018

[1] Committee for Medicinal Products for Human Use

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Procedural step:	**Date**
Rapporteurs' joint assessment report circulated to PRAC and to CHMP:	30 May 2018
Comments:	04 June 2018
Updated Rapporteurs' joint assessment report circulated to PRAC and to CHMP:	07 June 2018
PRAC second list of outstanding issues	June, 2018 PRAC
Scientific Advisory Group meeting:	19 June 2018
Submission of responses:	20 June 2018
Re-start of the procedure:	25 June 2018
Rapporteurs' joint assessment report circulated to PRAC and to CHMP:	29 June 2018
Comments:	4 July 2018
Updated Rapporteurs' joint assessment report circulated to PRAC and to CHMP:	6 July 2018
PRAC recommendation:	July, 2018 PRAC
CHMP opinion:	July, 2018 CHMP