EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

27 October 2016
EMA/PRAC/271123/2016 Rev.2

Timetable for the procedure

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

INVOKANA (canagliflozin) EMEA/H/A-20/1442/C/2649/0018

VOKANAMET (canagliflozin / metformin) EMEA/H/A-20/1442/C/2656-0014

FORXIGA (dapagliflozin) EMEA/H/A-20/1442/C/2322/0029

EDISTRIDE (dapagliflozin) EMEA/H/A-20/1442/C/4161/0010

XIGDUO (dapagliflozin/metformin) EMEA/H/A-20/1442/C/2672/0024

EBYMECT (dapagliflozin/metformin) EMEA/H/A-20/1442/C/4162/0013

JARDIANCE (empagliflozin) EMEA/H/A-20/1442/C/2677/0023

SYNJARDY (empagliflozin/metformin) EMEA/H/A-20/1442/C/3770/0022

Procedural step:	**Date**
Notification:	15 April 2016
Start of the procedure (PRAC):	15 April 2016 PRAC
List of questions:	21 April 2016
Submission of responses:	26 May 2016

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Procedural step:	Date
Re-start of the procedure:	09 June 2016
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]	20 June 2016
Comments:	27 June 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP	30 June 2016
PRAC list of questions & list of outstanding issues:	July 2016 PRAC
Submission of responses:	15 September 2016
Re-start of the procedure:	29 September 2016
Assessment report(s) circulated to PRAC and CHMP:	12 October 2016
Comments:	17 October 2016
Updated rapporteur/co-rapporteur assessment report(s) circulated to PRAC and CHMP:	20 October 2016
PRAC second list of outstanding issues:	November 2016 PRAC (24-27 October 2016)
Submission of responses:	29 December 2016
Re-start of the procedure:	12 January 2017
Assessment report(s) circulated to PRAC and CHMP:	25 January 2017
Comments:	31 January 2017
Updated rapporteur/co-rapporteur assessment report(s) circulated to PRAC and CHMP:	02 February 2017
PRAC third list of outstanding issues or PRAC recommendation to CHMP:	09 February 2017

[1] Committee for Medicinal Products for Human Use