8 October 2015
EMA/PRAC/391289/2015 rev. 1

Timetable for the procedure

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

SGLT2 inhibitors (canagliflozin, dapagliflozin, empagliflozin)

Invokana EMEA/H/A-20/1419/C/2649/0011

Vokanamet EMEA/H/A-20/1419/C/2656/0007

Forxiga EMEA/H/A-20/1419/C/2322/0021

XigDuo EMEA/H/A-20/1419/C/2672/0012

Jardiance EMEA/H/A-20/1419/C/2677/0007

Synjardy EMEA/H/A-20/1419/C/3770/0001

Procedural step:	**Date**
Notification:	10 June 2015
Start of the procedure (PRAC):	June 2015 PRAC
List of questions:	11 June 2015
Submission of responses:	14 August 2015
Re-start of the procedure:	10 September 2015
Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP[1]	23 September 2015
Comments:	28 September 2015

[1] Committee for Medicinal Products for Human Use

30 Churchill Place ● Canary Wharf ● London E14 5EU ● United Kingdom
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Send a question via our website www.ema.europa.eu/contact

Procedural step:	**Date**
Updated Rapporteur/co-rapporteur assessment reports circulated to PRAC and to CHMP:	1 October 2015
PRAC list of outstanding issues	October 2015 PRAC
Submission of responses:	08 December 2015
Re-start of the procedure:	14 January 2016
Joint assessment report(s) circulated to PRAC and CHMP:	15 January 2016
Comments:	27 January 2016
Updated Rapporteur/co-rapporteur assessment report(s) circulated to PRAC and CHMP:	02 February 2016
PRAC recommendation:	February 2016 PRAC