



15 September 2016
EMA/CHMP/50792/2016 Rev. 3

Timetable for the procedure

Referral under article 31 of Directive 2001/83/EC

Metformin containing medicinal products

Procedure no: EMEA/H/A-31/1432

Competact EMEA/H/A-31/1432/C/000655/0060, Ebymect EMEA/H/A-31/1432/C/004162/0007, Efficib EMEA/H/A-31/1432/C/000896/0078, Eucreas EMEA/H/A-31/1432/C/000807/0056, Glubrava EMEA/H/A-31/1432/C/000893/0045, Icandra EMEA/H/A-31/1432/C/001050/0056, Janumet EMEA/H/A-31/1432/C/000861/0077, Jentaduetto EMEA/H/A-31/1432/C/002279/0029, Komboglyze EMEA/H/A-31/1432/C/002059/0030, Ristfor EMEA/H/A-31/1432/C/001235/0065, Synjardy EMEA/H/A-31/1432/C/003370/0013, Velmetia EMEA/H/A-31/1432/C/000862/0081, Vipdomet EMEA/H/A-31/1432/C/002654/0015, Vokanamet EMEA/H/A-31/1432/C/002656/0013, Xigduo EMEA/H/A-31/1432/C/002672/0018, Zomarist EMEA/H/A-31/1432/C/001049/0056

Procedural step:	Date
Notification:	25 January 2016
Start of the procedure (CHMP):	January 2016 CHMP
List of questions:	January 2016 CHMP
Submission of responses:	12 May 2016
Re-start of the procedure:	26 May 2016
(Co-)Rapporteur assessment report(s) circulated to CHMP:	08 June 2016
Comments:	13 June 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	16 June 2016



Procedural step:	Date
CHMP list of outstanding issues:	June 2016 CHMP
Submission of responses:	04 August 2016
Re-start of the procedure:	18 August 2016
(Co-)Rapporteur assessment report(s) circulated to CHMP:	31 August 2016
Comments:	05 September 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	08 September 2016
CHMP 2nd list of outstanding issues:	15 September 2016
Submission of responses:	21 September 2016
Re-start of the procedure:	26 September 2016
(Co-)Rapporteur assessment report(s) circulated to CHMP:	30 September 2016
Comments:	05 October 2016
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	07 October 2016
CHMP Opinion:	13 October 2016