



13 December 2018  
EMA/CHMP/466973/2018 rev2

## Timetable for the procedure

### Referral under article 31 of Directive 2001/83/EC

Angiotensin-II-receptor antagonists (sartans) containing a tetrazole group

Procedure no: EMEA/H/A-31/1471

Nationally authorised products: various

Centrally authorised products:

Amlodipine-Valsartan Mylan EMEA/H/A-31/1471/C/4037/0004; Aprovel EMEA/H/A-31/1471/C/141/0172; Coaprovel EMEA/H/A-31/1471/C/222/0187; Copalia EMEA/H/A-31/1471/C/774/0099; Copalia HCT EMEA/H/A-31/1471/C/1159/0069; Dafiro EMEA/H/A-31/1471/C/776/0101; Dafiro HCT EMEA/H/A-31/1471/C/1160/0070; Entresto EMEA/H/A-31/1471/C/4062/0021; Exforge EMEA/H/A-31/1471/C/716/0098; Exforge HCT EMEA/H/A-31/1471/C/1068/0068; Ifirmacombi EMEA/H/A-31/1471/C/2302/0020; Ifirmasta EMEA/H/A-31/1471/C/962/0018; Irbesartan Hydrochlorothiazide Zentiva EMEA/H/A-31/1471/C/783/0101; Irbesartan Teva EMEA/H/A-31/1471/C/1093/0032; Irbesartan Zentiva EMEA/H/A-31/1471/C/785/0080; Irbesartan/Hydrochlorothiazide Teva EMEA/H/A-31/1471/C/1112/A31/0041; Karvea EMEA/H/A-31/1471/C/142/0175; Karvezide EMEA/H/A-31/1471/C/221/0188; Neparvis EMEA/H/A-31/1471/C/4343/0020

Active substances: candesartan, irbesartan, losartan, olmesartan, valsartan

Procedural step:	Date
Notification:	5 July 2018
Start of the procedure (CHMP):	16 July 2018
List of questions:	16 July 2018
Submission of responses:	30 July 2018



<b>Procedural step:</b>	<b>Date</b>
Re-start of the procedure:	23 August 2018
Rapporteur/Co-rapporteur assessment report(s) circulated to CHMP:	10 September 2018
CHMP comments:	13 September 2018
Updated Rapporteur/co-rapporteur assessment reports circulated to CHMP:	14 September 2018
CHMP lists of outstanding issues:	20 September 2018
Submission of responses:	31 October 2018
Re-start of the procedure:	15 November 2018
Joint assessment report circulated to CHMP:	28 November 2018
CHMP comments:	03 December 2018
Updated joint assessment report circulated to CHMP:	06 December 2018
CHMP second list of outstanding issues or	December 2018
Submission of responses:	3 January 2019
Re-start of the procedure:	4 January 2019
Joint assessment report circulated to CHMP:	15 January 2019
CHMP comments:	21 January 2019
Updated joint assessment report circulated to CHMP:	24 January 2019
CHMP opinion:	January 2019