EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 October 2020
EMA/CHMP/525148/2020

# Timetable for the procedure – CHMP Opinion on the impact of the Article 5(3) referral on nitrosamines in human medicinal products on the referral under article 31 of Directive 2001/83/EC for sartans medicinal products containing a tetrazole ring

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** |
|---|---|
| Request from EC for a CHMP Opinion: | 29 July 2020 |
| (Joint) Assessment Report circulated to CHMP: | 24 October 2020 |
| Comments: | 30 October 2020 |

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| **Procedural step:** | **Date** |
|---|---|
| Updated (joint) assessment report circulated to CHMP: | 5 November 2020 |
| CHMP opinion: | November 2020 CHMP |