



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/413747/2020

## European Medicines Agency decision P/0315/2020

of 14 August 2020

on the granting of a product specific waiver for sacubitril / valsartan (Entresto and associated names), (EMA-000316-PIP03-20) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Only the English text is authentic.**



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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004<sup>1</sup>,

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency<sup>2</sup>,

Having regard to the application submitted by Novartis Europharm Ltd. on 25 March 2020 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 June 2020 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

- (1) The Paediatric Committee has given an opinion on the granting of a product specific waiver.
- (2) It is therefore appropriate to adopt a decision granting a waiver.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A waiver for sacubitril / valsartan (Entresto and associated names), film-coated tablet, granules, age-appropriate oral solid dosage form, oral use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

**Article 2**

This decision is addressed to Novartis Europharm Ltd., Vista Building Elm Park Merrion Road, D04 A9N6 - Dublin 4 Ireland.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/196780/2020  
Amsterdam, 26 June 2020

## Opinion of the Paediatric Committee on the granting of a product-specific waiver

EMA-000316-PIP03-20

### Scope of the application

**Active substance(s):**

Sacubitril / valsartan

**Invented name:**

Entresto and associated names

**Condition(s):**

Prevention of heart failure

**Authorised indication(s):**

See Annex II

**Pharmaceutical form(s):**

Film-coated tablet

Granules

Age-appropriate oral solid dosage form

**Route(s) of administration:**

Oral use

**Name/corporate name of the PIP applicant:**

Novartis Europharm Ltd.

**Information about the authorised medicinal product:**

See Annex II



## **Basis for opinion**

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Novartis Europharm Ltd. submitted to the European Medicines Agency on 25 March 2020 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.

The procedure started on 30 April 2020.

## **Opinion**

1. The Paediatric Committee, having assessed the waiver application in accordance with Article 13 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:
  - to grant a product-specific waiver for all subsets of the paediatric population the above mentioned condition in accordance with Article 11(1)(c) of said Regulation, on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The grounds for the granting of the waiver are set out in Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annexes and appendix.

## **Annex I**

### **Grounds for the granting of the waiver**

# 1. Waiver

## **1.1. Condition:**

Prevention of heart failure

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- film-coated tablet, granules, age-appropriate oral solid dosage form, oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

## **Annex II**

### **Information about the authorised medicinal product**



**Condition(s) and authorised indication(s):**

1. Treatment of heart failure

Authorised indication(s):

- Entresto is indicated in adult patients for treatment of symptomatic chronic heart failure with reduced ejection fraction

**Authorised pharmaceutical form(s):**

Film-coated tablets

**Authorised route(s) of administration:**

Oral use