



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/707275/2021

## European Medicines Agency decision P/0557/2021

of 31 December 2021

on the granting of a product-specific waiver for paracetamol / acetylcysteine / phenylephrine (EMA-003091-PIP01-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Only the English text is authentic.**



# European Medicines Agency decision

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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 Hexal AG on 9 August 2021 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 12 November 2021 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.

Has adopted this decision:

## **Article 1**

A product-specific waiver for paracetamol / acetylcysteine / phenylephrine, granules for oral solution, 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 HEXAL AG, Industriestrasse 25, 83607 – Holzkirchen, Germany.

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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.



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EMA/PDCO/496753/2021  
Amsterdam, 12 November 2021

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

EMA-003091-PIP01-21

### Scope of the application

**Active substance(s):**

Paracetamol / acetylcysteine / phenylephrine

**Condition(s):**

Treatment of upper respiratory tract infections

**Pharmaceutical form(s):**

Granules for oral solution

**Route(s) of administration:**

Oral use

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

Hexal AG

### Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Hexal AG submitted to the European Medicines Agency on 9 August 2021 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 14 September 2021.

### 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 and the above mentioned condition(s) 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 annex and appendix.

## **Annex I**

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

# 1. Waiver

## **1.1. Condition:**

Treatment of upper respiratory tract infections

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- granules for oral solution;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.