EMADOC-1700519818-1855159

European Medicines Agency decision

EMA/PE/0000226288

of 28 January 2025

on the granting of a product specific waiver for dupilumab 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[1],

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

Having regard to the application submitted by Sanofi Winthrop Industrie on 29 August 2024 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 13 December 2024 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 waiver for dupilumab, 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 Sanofi Winthrop Industrie, 82 Avenue Raspail, 94250 - Gentilly, France.

[1] OJ L 378, 27.12.2006, p.1, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

EMADOC-1700519818-1685412
Amsterdam, 13 December 2024

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

EMA/PE/0000226288

Scope of the application

Active substance(s):

Dupilumab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of lichen simplex chronicus

Pharmaceutical form(s):

Solution for injection

Route(s) of administration:

Subcutaneous use

Name/corporate name of the PIP applicant:

Sanofi Winthrop Industrie

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Sanofi Winthrop Industrie submitted to the European Medicines Agency on 29 August 2024 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 October 2024.

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 Paediatric Committee members of Liechtenstein and Norway agree 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:

Treatment of lichen simplex chronicus

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- solution for injection, subcutaneous use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies are not feasible.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

Condition(s) and authorised indication(s)

1. Treatment of atopic dermatitis

Authorised indication(s):

- Treatment of moderate-to-severe atopic dermatitis in adults and adolescents 12 years and older who are candidates for systemic therapy
  - Invented name: Dupixent
  - Authorised pharmaceutical form: Solution for injection
  - Authorised route of administration: Subcutaneous use
  - Authorised via centralised procedure
- Treatment of severe atopic dermatitis in children 6 months to 11 years old who are candidates for systemic therapy
  - Invented name: Dupixent
  - Authorised pharmaceutical form: Solution for injection
  - Authorised route of administration: Subcutaneous use
  - Authorised via centralised procedure

2. Treatment of asthma

- Dupixent is indicated in adults and adolescents 12 years and older as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), see section 5.1, who are inadequately controlled with high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment
  - Invented name: Dupixent
  - Authorised pharmaceutical form: Solution for injection
  - Authorised route of administration: Subcutaneous use
  - Authorised via centralised procedure
- Dupixent is indicated in children 6 to 11 years old as add-on maintenance treatment for severe asthma with type 2 inflammation characterised by raised blood eosinophils and/or raised fraction of exhaled nitric oxide (FeNO), see section 5.1, who are inadequately controlled with medium to high dose inhaled corticosteroids (ICS) plus another medicinal product for maintenance treatment
  - Invented name: Dupixent
  - Authorised pharmaceutical form: Solution for injection
  - Authorised route of administration: Subcutaneous use
  - Authorised via centralised procedure

3. Treatment of chronic rhinosinusitis with nasal polyposis (CRSwNP)

- Dupixent is indicated as an add-on therapy with intranasal corticosteroids for the treatment of adults with severe CRSwNP for whom therapy with systemic corticosteroids and/or surgery do not provide adequate disease control

  - Invented name: Dupixent
  - Authorised pharmaceutical form: Solution for injection
  - Authorised route of administration: Subcutaneous use
  - Authorised via centralised procedure

4. Treatment of prurigo nodularis (PN)

- Dupixent is indicated for the treatment of adults with moderate-to-severe prurigo nodularis (PN) who are candidates for systemic therapy

  - Invented name: Dupixent
  - Authorised pharmaceutical form: Solution for injection
  - Authorised route of administration: Subcutaneous use
  - Authorised via centralised procedure

5. Treatment of eosinophilic esophagitis (EoE)

- Dupixent is indicated for the treatment of eosinophilic esophagitis in adults, adolescents and children aged 1 year and older, weighing at least 15 kg, who are inadequately controlled by, are intolerant to, or who are not candidates for conventional medicinal therapy

  - Invented name: Dupixent
  - Authorised pharmaceutical form: Solution for injection
  - Authorised route of administration: Subcutaneous use
  - Authorised via centralised procedure

6. Treatment of chronic obstructive pulmonary disease (COPD)

- Dupixent is indicated in adults as add-on maintenance treatment for uncontrolled chronic obstructive pulmonary disease (COPD) characterised by raised blood eosinophils on a combination of an inhaled corticosteroid (ICS), a long-acting beta2-agonist (LABA), and a long-acting muscarinic antagonist (LAMA), or on a combination of a LABA and a LAMA if ICS is not appropriate

  - Invented name: Dupixent
  - Authorised pharmaceutical form: Solution for injection
  - Authorised route of administration: Subcutaneous use
  - Authorised via centralised procedure