EMA/12352/2022

European Medicines Agency decision

P/0027/2022

of 31 January 2022

on the granting of a product specific waiver for fostamatinib (Tavlesse), (EMEA-001196-PIP03-21) 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

P/0027/2022

of 31 January 2022

on the granting of a product specific waiver for fostamatinib (Tavlesse), (EMEA-001196-PIP03-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 Instituto Grifols, S.A. on 10 September 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 17 December 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 waiver for fostamatinib (Tavlesse), all pharmaceutical forms, all routes of administration, 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 Instituto Grifols, S.A., 2 Can Guasch St., Polígono Levante, 08150 - Parets del Vallès, Spain.

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

EMA/PDCO/549540/2021
Amsterdam, 17 December 2021

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

EMEA-001196-PIP03-21

Scope of the application

Active substance(s):

Fostamatinib

Invented name:

Tavlesse

Condition(s):

Treatment of autoimmune haemolytic anaemia

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

All pharmaceutical forms

Route(s) of administration:

All routes of administration

Name/corporate name of the PIP applicant:

Instituto Grifols, S.A.

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Instituto Grifols, S.A. submitted to the European Medicines Agency on 10 September 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 19 October 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all of the paediatric population.

   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:

Treatment of autoimmune haemolytic anaemia

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- all pharmaceutical forms, all routes of administration;
- on the grounds that the specific medicinal product is likely to be unsafe.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of immune thrombocytopenia (idiopathic thrombocytopenic purpura)

Authorised indication(s):

- Tavlesse is indicated for the treatment of chronic immune thrombocytopenia (ITP) in adult patients who are refractory to other treatments

Authorised pharmaceutical form(s):

Film-coated tablet

Authorised route(s) of administration:

Oral use