



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/602315/2022

European Medicines Agency decision P/0235/2022

of 8 July 2022

on the granting of a product specific waiver for trabectedin (Yondelis), (EMEA-000610-PIP02-22) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by Pharma Mar, S.A. on 21 February 2022 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 20 May 2022 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 trabectedin (Yondelis), 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 Pharma Mar, S.A., Avda. de los Reyes, 1 Pol. Ind. La Mina, 28770 - Colmenar Viejo, Spain.

¹ OJ L 378, 27.12.2006, p.1, as amended.

² OJ L 136, 30.4.2004, p. 1, as amended.



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EMA/PDCO/145279/2022
Amsterdam, 20 May 2022

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

EMA-000610-PIP02-22

Scope of the application

Active substance(s):

Trabectedin

Invented name:

Yondelis

Condition(s):

Treatment of soft tissue sarcoma

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:

Pharma Mar, 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, Pharma Mar, S.A. submitted to the European Medicines Agency on 21 February 2022 an application for a product-specific waiver on the grounds set out in Article 11 of said Regulation for the above mentioned medicinal product.



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 Paediatric Committee member of Norway 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 soft tissue sarcoma

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 ineffective.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of soft tissue sarcoma

Authorised indication(s):

- The treatment of adult patients with advanced soft tissue sarcoma, after failure of anthracyclines and ifosfamide, or who are unsuited to receive these agents. Efficacy data are based mainly on liposarcoma and leiomyosarcoma patients.

2. Treatment of ovarian cancer

Authorised indication(s):

- Yondelis in combination with pegylated liposomal doxorubicin (PLD) for the treatment of patients with relapsed platinum-sensitive ovarian cancer.

Authorised pharmaceutical form(s):

Powder for concentrate for solution for infusion

Authorised route(s) of administration:

Intravenous use