



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1690068

European Medicines Agency decision

EMA/PE/0000181891

of 25 October 2024

on the granting of a product specific waiver for sildenafil citrate, testosterone (EMA/PE/0000181891)
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 Freya Pharma Solutions Holding B.V. on 28 June 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 6 September 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 sildenafil citrate, testosterone, sublingual use, 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 Freya Pharma Solutions Holding B.V., Kraanspoor 50, 1033 SE – Amsterdam, Netherlands.

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

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



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Amsterdam, 6 September 2024
EMADOC-1700519818-1620875

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

EMA/PE/0000181891

Scope of the application

Active substance(s):

Sildenafil citrate, testosterone

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hypoactive sexual desire disorder

Pharmaceutical form(s):

Film-coated tablet

Route(s) of administration:

Sublingual use

Oral use

Name/corporate name of the PIP applicant:

Freya Pharma Solutions Holding B.V.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, Freya Pharma Solutions Holding B.V. submitted to the European Medicines Agency on 28 June 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 19 August 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 by consensus as set out in the appended summary report:
 - to grant a product-specific waiver for all subsets of the paediatric population in 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.
2. The Paediatric Committee member of Norway agrees with the above-mentioned recommendation of the Paediatric Committee.

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

1. Waiver

1.1. Condition:

Treatment of hypoactive sexual desire disorder

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- film-coated tablet, sublingual use and oral use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.