



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/666635/2017

European Medicines Agency decision P/0304/2017

of 31 October 2017

on the granting of a product specific waiver for meldonium (dihydrate) (EMA-002212-PIP01-17) 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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on the granting of a product specific waiver for meldonium (dihydrate) (EMA-002212-PIP01-17) 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 726/2004¹,

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 Agency²,

Having regard to the application submitted by ELC GROUP s.r.o. on 9 June 2017 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 15 September 2017 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 meldonium (dihydrate), capsule, hard, 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 ELC GROUP s.r.o., Karolinská 650/1, Karlín, 186 00 - Prague 8, Czech Republic.

¹ OJ L 378, 27.12.2006, p.1.

² OJ L 136, 30.4.2004, p. 1.



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EMA/PDCO/457979/2017

London, 15 September 2017

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

EMA-002212-PIP01-17

Scope of the application

Active substance(s):

Meldonium (dihydrate)

Condition(s):

Treatment of angina pectoris

Pharmaceutical form(s):

Capsule, hard

Route(s) of administration:

Oral use

Name / corporate name of the PIP applicant:

ELC GROUP s.r.o.

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, ELC GROUP s.r.o. submitted to the European Medicines Agency on 9 June 2017 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 18 July 2017.



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)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended occurs only in adult populations.

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 angina pectoris

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- capsule, hard, oral use;
- on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified paediatric subset(s).