EMA/705362/2022

European Medicines Agency decision

P/0373/2022

of 9 September 2022

on the acceptance of a modification of an agreed paediatric investigation plan for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), (EMEA-000181-PIP02-13-M01) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

Disclaimer

This decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

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 European Medicines Agency's decision P/0298/2014 issued on 24 November 2014,

Having regard to the application submitted by GW Pharma (International) B.V on 12 April 2022 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and proposing a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 22 July 2022, in accordance with Article 22 of Regulation (EC) No 1901/2006 and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the acceptance of changes to the agreed paediatric investigation plan and to the deferral and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision on the acceptance of changes to the agreed paediatric investigation plan, including changes to the deferral.

(3) It is therefore appropriate to adopt a decision granting a waiver.

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), oromucosal spray, oromucosal use, including changes to the deferral, are hereby accepted in the scope set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices.

Article 2

A waiver for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), oromucosal spray, oromucosal use, the details of which are set out in the opinion of the Paediatric Committee the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

Article 3

This decision covers all conditions, indications, pharmaceutical forms, routes of administration, measures, timelines, waivers and deferrals, as agreed in the decision P/41/2009 issued on 23 March 2009, including subsequent modifications thereof.

Article 4

This decision is addressed to GW Pharma (International) B.V, Databankweg 26, 3821AL - Amersfoort, Netherlands.

EMA/PDCO/250337/2022
Amsterdam, 22 July 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan and on the granting of a product-specific waiver

EMEA-000181-PIP02-13-M01

Scope of the application

Active substance(s):

Cannabidiol / delta-9-tetrahydrocannabinol

Invented name:

Sativex

Condition(s):

Treatment of pain

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oromucosal spray

Route(s) of administration:

Oromucosal use

Name/corporate name of the PIP applicant:

GW Pharma (International) B.V

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GW Pharma (International) B.V submitted to the European Medicines Agency on 12 April 2022 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0298/2014 issued on 24 November 2014.

The application for modification proposed changes to the agreed paediatric investigation plan and to the deferral and proposed a waiver for all subsets of the paediatric population.

The procedure started on 23 May 2022.

Scope of the modification

Closure of this Paediatric Investigation Plan and granting a product-specific waiver.

Opinion

1. The Paediatric Committee, having assessed the application in accordance with Article 22 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree to changes to the paediatric investigation plan and to the deferral in the scope set out in the Annex I of this opinion;
   - to grant a product-specific waiver for all subsets of the paediatric population concluded 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 pain

The waiver applies to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for oromucosal spray, oromucosal use;
- on the grounds that the specific medicinal product is likely to be ineffective and unsafe.

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of spasticity

Authorised indication(s):

- Sativex is indicated as treatment for symptom improvement in patients with moderate to severe spasticity due to multiple sclerosis (MS) who have not responded adequately to other anti-spasticity medication and who demonstrate clinically significant improvement in spasticity related symptoms during an initial trial of therapy. (Adults)

Authorised pharmaceutical form(s):

Oromucosal spray

Authorised route(s) of administration:

Oromucosal use