EMA/145466/2022

European Medicines Agency decision

P/0110/2022

of 13 April 2022

on the acceptance of a modification of an agreed paediatric investigation plan for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), (EMEA-000181-PIP01-08-M06) 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/41/2009 issued on 23 March 2009, the decision P/0290/2012 issued on 18 December 2012 and the decision P/0316/2016 issued on 2 December 2016,

Having regard to the application submitted by GW Pharma (International) B.V on 19 November 2021 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 25 February 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, oral 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, oral 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 is addressed to GW Pharma (International) B.V, Databankweg 26, 3821AL - Amersfoort, The Netherlands.

EMA/PDCO/709216/2021
Amsterdam, 25 February 2022

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan

EMEA-000181-PIP01-08-M06

Scope of the application

Cannabidiol / delta-9-tetrahydrocannabinol

Invented name:

Sativex

Condition(s):

Treatment of spasticity

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Oromucosal spray

Route(s) of administration:

Oral 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 19 November 2021 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/41/2009 issued on 23 March 2009, the decision P/0290/2012 issued on 18 December 2012 and the decision P/0316/2016 issued on 2 December 2016.

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

The procedure started on 4 January 2022.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified. A waiver for a new paediatric subset has been added.

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 waiver for one or more 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 Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the 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

The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

1. Waiver

1.1. Condition:

Treatment of spasticity

The waiver applies to:

- the paediatric population from birth to less than 8 years of age;
- oromucosal spray, oral use;
- on the grounds that the specific medicinal product is likely to be ineffective and unsafe.

2. Paediatric Investigation Plan

2.1. Condition:

Treatment of spasticity

2.1.1. Indication(s) targeted by the PIP

Intractable spasticity due to cerebral palsy or traumatic CNS injury

2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

From 8 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Oromucosal spray for oral use

2.1.4. Measures

Area	**Description**
Quality	Not applicable
Non-clinical	Not applicable
Clinical	**Study 1** The efficacy, safety and tolerability of cannabidiol, delta-9-tetrahydrocannabinol as an adjunctive treatment to existing anti-spasticity medications in children aged 8 to 18 years with spasticity due to cerebral palsy or traumatic central nervous system injury who have not responded adequately to their existing anti-spasticity medications: a parallel group randomised, double-blind, placebo-controlled study followed by a 24-week open-label extension phase (GWSP08258) **Study 2** Deleted in procedure EMEA-000181-PIP01-08-M06

Extrapolation, modelling and simulation studies	Not applicable
Other studies	Not applicable
Other measures	Not applicable

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety and efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By April 2017
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Condition(s) and authorised indication(s):

1. Treatment of spasticity

Authorised indications:

- 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.

Authorised pharmaceutical formulation(s):

Oromucosal spray

Authorised route(s) of administration:

Oromucosal use