EMA/641622/2014

European Medicines Agency decision

P/0298/2014

of 24 November 2014

on the agreement of a paediatric investigation plan and on the granting of a deferral for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), (EMEA-000181-PIP02-13) 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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on the agreement of a paediatric investigation plan and on the granting of a deferral for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), (EMEA-000181-PIP02-13) 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 726/2004[1],

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 Agency[2],

Having regard to the application submitted by GW Pharma Ltd on 5 August 2013 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 10 October 2014, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 21 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 agreement of a paediatric investigation plan and on the granting of a deferral.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

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

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

Has adopted this decision:

Article 1

A paediatric investigation plan for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), oromucosal spray, oromucosal 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 agreed.

Article 2

A deferral for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), oromucosal spray, oromucosal 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 3

This agreed PIP 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 Ltd, Porton Down Science Park, SP4 0JQ – Salisbury, United Kingdom.

Done at London, 24 November 2014

For the European Medicines Agency
Zaide Frias
Head of Division (ad interim)
Human Medicines Research and Development Support
(Signature on file)

EMA/PDCO/434446/2014

Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a deferral

EMEA-000181-PIP02-13

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 Ltd

Information about the authorised medicinal product:

See Annex II

Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, GW Pharma Ltd submitted for agreement to the European Medicines Agency on 5 August 2013 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 12 September 2013.

Supplementary information was provided by the applicant on 4 July 2014. The applicant proposed modifications to the paediatric investigation plan and withdrew its request for a waiver.

Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation;
   - to grant a deferral in accordance with Article 21 of said Regulation.

   The Icelandic and the Norwegian Paediatric Committee members agree with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan 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.

London, 10 October 2014

On behalf of the Paediatric Committee
Dr Dirk Mentzer, Chairman
(Signature on file)

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 (PIP)

1. Waiver

Not applicable.

2. Paediatric investigation plan

2.1. Condition:

Treatment of pain

2.1.1. Indication(s) targeted by the PIP

Treatment of chronic pain in palliative care when optimal treatment with opiates is not fully effective

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

From birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Oromucosal spray

2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Development of an age-appropriate lower-strength oromucosal spray formulation containing 13.5 mg/ml delta-9-tetrahydrocannabinol and 12.5 mg/ml cannabidiol
Non-clinical studies	0	Not applicable.
Clinical studies	2	Study 2: Double-blind, placebo-controlled safety and efficacy study of cannabidiol / delta-9-tetrahydrocannabinol (Sativex) as adjunctive therapy to opiates in paediatric patients from 8 to less than 18 years of age with cancer-related pain; followed by a long-term, open-label extension phase. Study 3: Double-blind, placebo-controlled safety and efficacy study of cannabidiol / delta-9-tetrahydrocannabinol (Sativex) as adjunctive therapy to opiates in paediatric patients from birth to less than 8 years of age with cancer-related pain; followed by a long-term, open-label extension phase.

Area	Number of measures	Description
Extrapolation, modelling and simulation studies	0	Not applicable.
Other studies	0	Not applicable.
Other measures	0	Not applicable.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By July 2026
Deferral for one or more measures 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 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