EMA/737330/2012

European Medicines Agency decision

P/0290/2012

of 18 December 2012

on the acceptance of a modification of an agreed paediatric investigation plan for cannabidiol / delta-9-tetrahydrocannabinol (Sativex) (EMEA-000181-PIP01-08-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 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 European Medicines Agency's decision P/41/2009 issued on 23 March 2009,

Having regard to the application submitted by GW Pharma Ltd on 7 August 2012 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 9 November 2012, in accordance with Article 22 of Regulation (EC) No 1901/2006,

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.

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

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

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for cannabidiol / delta-9-tetrahydrocannabinol (Sativex), oromucosal spray, oral use, 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

This decision is addressed to GW Pharma Ltd, Porton Down Science Park, SP4 0JQ - Salisbury, Wiltshire, United Kingdom.

Done at London, 18 December 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/557948/2012

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

EMEA-000181-PIP01-08-M01

Scope of the application

Active substance(s):

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 Ltd

Information about the authorised medicinal product:

See Annex II

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Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GW Pharma Ltd submitted to the European Medicines Agency on 7 August 2012 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 application for modification proposed changes to the agreed paediatric investigation plan.

The procedure started on 12 September 2012.

Scope of the modification

Some measures and timelines of the Paediatric Investigation Plan have been modified.

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 in the scope set out in the Annex I of this opinion.

   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 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, 9 November 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, 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

1. Waiver

Not applicable

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 birth to less than 18 years of age.

2.1.3. Pharmaceutical form(s)

Oromucosal spray for oral use.

2.1.4. Studies

Area	Number of studies	Description
Quality	0	Not applicable.
Non-clinical	0	Not applicable.
Clinical	2	**Study 1** Double blind, randomized multicenter, placebo controlled trial to evaluate efficacy, safety and pharmacokinetics of cannabidiol, delta-9-tetrahydrocannabinol as an add-on treatment in children from 8 to less than 18 years of age with intractable spasticity due to cerebral palsy or traumatic CNS injury (GWSP08258). **Study 2** Double blind, randomized multicenter, placebo controlled trial to evaluate efficacy, safety and pharmacokinetics of cannabidiol, delta-9-tetrahydrocannabinol as an add-on treatment in children less than 8 years of age with intractable spasticity due to cerebral palsy or traumatic CNS injury.

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 December 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