EMA/324452/2018

European Medicines Agency decision

P/0161/2018

of 15 June 2018

on the acceptance of a modification of an agreed paediatric investigation plan for spheroids of human autologous matrix-associated chondrocytes (Spherox), (EMEA-001264-PIP01-12-M02) 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/0253/2012 issued on 30 November 2012,

Having regard to the application submitted by CO.DON AG on 5 February 2018 under Article 22 of Regulation (EC) No 1901/2006 proposing changes to the agreed paediatric investigation plan with a deferral and a waiver,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 27 April 2018, 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 spheroids of human autologous matrix-associated chondrocytes (Spherox), implantation suspension, intraarticular 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 CO.DON AG, Warthestraße 21, 14513 - Teltow, Germany.

EMA/PDCO/79344/2018
London, 27 April 2018

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

EMEA-001264-PIP01-12-M02

Scope of the application

Active substance(s):

Spheroids of human autologous matrix-associated chondrocytes

Invented name:

Spherox

Condition(s):

Treatment of cartilage disorders

Authorised indication(s):

See Annex II

Pharmaceutical form(s):

Implantation suspension

Route(s) of administration:

Intraarticular use

Name/corporate name of the PIP applicant:

CO.DON AG

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, CO.DON AG submitted to the European Medicines Agency on 5 February 2018 an application for modification of the agreed paediatric investigation plan with a deferral and a waiver as set out in the European Medicines Agency's decision P/0253/2012 issued on 30 November 2012.

The application for modification proposed changes to the agreed paediatric investigation.

The procedure started on 27 February 2018.

Scope of the modification

Some measures 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 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 (PIP)

1. Waiver

1.1. Condition

Treatment of cartilage disorders

The waiver applies to:

- the paediatric population from birth to 15 years of age;
- implantation suspension, intraarticular use;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit over existing treatments.

2. Paediatric Investigation Plan

2.1. Condition

Treatment of cartilage disorders

2.1.1. Indication(s) targeted by the PIP

Treatment of cartilage disorders

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

From 15 to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Implantation suspension for intraarticular use

2.1.4. Measures

Area	Number of studies	Description
Quality-relates studies	0	Not applicable.
Non-clinical studies	0	Not applicable.
Clinical studies	1	**Study 1** Prospective non-interventional investigation to evaluate the long-term safety and linked efficacy of the three-dimensional autologous chondrocyte implantation product in paediatric patients from 15 to less than 18 years of age treated with the product.

3. Follow-up, completion and deferral of PIP

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	Yes
Date of completion of the paediatric investigation plan:	By June 2020
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 cartilage disorders

Authorised indication(s):

- Repair of symptomatic articular cartilage defects of the femoral condyle and the patella of the knee

Authorised pharmaceutical form(s):

Implantation suspension

Authorised route(s) of administration:

Intraarticular use