EMA/657489/2016

# European Medicines Agency decision

P/0280/2016

of 12 October 2016

on the acceptance of a modification of an agreed paediatric investigation plan for recombinant human nerve growth factor (EMEA-001729-PIP01-14-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/0177/2015 issued on 7 August 2015,

Having regard to the application submitted by Dompé farmaceutici SpA on 27 June 2016 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 16 September 2016, 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 recombinant human nerve growth factor, eye drops, solution, ocular 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 Dompé farmaceutici S.p.A., Via Santa Lucia, 6, 20122 – Milan, Italy.

EMA/PDCO/456665/2016
London, 16 September 2016

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

EMEA-001729-PIP01-14-M01

## Scope of the application

**Active substance(s):**

Recombinant human nerve growth factor

**Condition(s):**

Treatment of neurotrophic keratitis

**Pharmaceutical form(s):**

Eye drops, solution

**Route(s) of administration:**

Ocular use

**Name/corporate name of the PIP applicant:**

Dompé farmaceutici SpA

## Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Dompé farmaceutici SpA submitted to the European Medicines Agency on 27 June 2016 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0177/2015 issued on 7 August 2015.

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

The procedure started on 19 July 2016.

## Scope of the modification

Some 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 Norwegian Paediatric Committee member agrees 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 annex 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

Not applicable.

# 2. Paediatric investigation plan

## *2.1. Condition:*

Treatment of neurotrophic keratitis

### 2.1.1. Indication(s) targeted by the PIP

Treatment of neurotrophic keratitis

### 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)

Eye drops, solution

### 2.1.4. Measures

| Area | Number of measures | Description |
|---|---|---|
| Quality-related studies | 0 | Not applicable. |
| Non-clinical studies | 2 | **Study 1**<br>Definitive juvenile toxicity study in rats for 30 days<br>**Study 2**<br>Definitive juvenile toxicity study in rabbits for 125 days |
| Clinical studies | 0 | Not applicable. |
| Extrapolation, modelling and simulation studies | 1 | **Study 3**<br>Qualitative review of (a) juvenile animal toxicology data from rat and rabbit and (b) human clinical data from a phase II study in adults with neurotrophic keratitis, leading to adoption of recommendations for SmPC advice regarding paediatric use |
| 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 April 2017 |
| Deferral for one or more measures contained in the paediatric investigation plan: | Yes |

## 6. Reminder

Interventional clinical trials have to be registered with the EudraCT database.

All investigational medicinal products used in the studies or trials must be registered in the EudraVigilance Medicinal Product Dictionary by the sponsor.

Studies or trials which are inconclusive or not interpretable will be considered non-compliant.

The Clinical trials should be performed in accordance with Good Clinical Practice. Those conducted outside the community should be carried out in accordance with the ethical standards of Directive 2001/20/EC and those conducted within the community should be carried out in accordance with Directive 2001/20/EC.

Applicants are reminded that it is their responsibility to submit a request for modification of an agreed paediatric investigation plan, if they encounter difficulties with its implementation which render the plan unworkable or no longer appropriate.

Applicants are also reminded that in order to verify compliance with the agreed PIP, the study report must be submitted for any study that had to be completed (see Commission Guideline 2014/C338/01 of 27 September 2014 and EMA procedural advice). This is part of the validation of the application for marketing authorisation, variation or line extension. Applicants are therefore advised to consider the time necessary to produce the appropriate report for their planned date of submission. For authorised medicinal products, reports need to be submitted to the competent authority within 6 months of completion of the studies, according to article 46 of Regulation (EC) No 1901/2006.