



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1976294

## European Medicines Agency decision

EMA/PE/0000232890

of 21 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for clevidipine (Cleviprex and associated names) 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.**



# European Medicines Agency decision

EMA/PE/0000232890

of 21 March 2025

on the acceptance of a modification of an agreed paediatric investigation plan for clevidipine (Cleviprex and associated names) 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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the European Medicines Agency's decision P/37/2009 issued on 23 February 2009, the decision P/0095/2012 issued on 30 May 2012 and the decision P/0009/2014 issued on 22 January 2014,

Having regard to the application submitted by Chiesi Farmaceutici S.p.A on 18 October 2024 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 31 January 2025, 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 and to the deferral.
- (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.

---

<sup>1</sup> OJ L 378, 27.12.2006, p.1, as amended.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

**Article 1**

Changes to the agreed paediatric investigation plan for clevidipine (Cleviprex and associated names), 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**

This decision is addressed to Chiesi Farmaceutici S.p.A., Via Palermo 26 A, 43122 – Parma, Italy.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMADOC-1700519818-1738032  
Amsterdam, 31 January 2025

## Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA/PE/0000232890

### Scope of the application

**Active substance(s):**

Clevidipine

**Invented name and authorisation status:**

See Annex II

**Condition(s):**

Treatment of hypertensive disease

**Pharmaceutical form(s):**

Emulsion for injection

**Route(s) of administration:**

Intravenous use

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

Chiesi Farmaceutici S.p.A.

### Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Chiesi Farmaceutici S.p.A. submitted to the European Medicines Agency on 18 October 2024 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/37/2009 issued on 23 February 2009, the decision P/0095/2012 issued on 30 May 2012 and the decision P/0009/2014 issued on 22 January 2014.

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

The procedure started on 25 November 2024.



## 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 and to the deferral in the scope set out in the Annex I of this opinion.

The Paediatric Committee member of Norway 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 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

Not applicable.

## 2. Paediatric Investigation Plan

### 2.1. Condition:

Treatment of hypertensive disease

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

Acute blood pressure management in paediatric patients

#### 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)

Emulsion for injection

#### 2.1.4. Measures

Area	Description
Quality	Not applicable.
Non-clinical	Not applicable.
Clinical	<p><b>Study 1:</b></p> <p>Open-label study in adolescents from 12 years to less than 18 years of age to assess the safety and pharmacodynamics of clevidipine in paediatric patients undergoing a surgical procedure requiring anaesthesia, and for whom parenteral IV antihypertensive therapy for blood pressure management is expected (MDCO-CLV-12-01 (PIONEER)).</p> <p><b>Study 2:</b></p> <p><i>Study added in procedure EMA/PE/0000232890</i></p> <p>Open-label, single-arm, baseline-controlled study to assess the safety, pharmacokinetics (PK) and pharmacodynamics (PD) of clevidipine given as continuous intravenous infusion in hospitalized paediatric patients from birth to less than 18 years of age who require acute reduction in blood pressure, when oral therapy is not feasible or not desirable.</p> <p><b>Study 3:</b></p> <p><i>Study added in procedure EMA/PE/0000232890</i></p>

Area	Description
	<p>Population pharmacokinetic model to assist dose selection (starting dose and maximum dose, based on adult exposure range) of clevidipine to be tested in paediatric patients in study 2.</p> <p><b>Study 4:</b></p> <p><i>Study added in procedure EMA/PE/0000232890</i></p> <p>Population pharmacokinetic/pharmacodynamic model to explore potential difference in the exposure-response relationship among patients of different ages to possibly support the dose selection (starting dose and maximum dose) of clevidipine to be tested in paediatric patients in study 2.</p>
Extrapolation plan	PIP studies 2, 3 and 4 together with TMC-CLV-06-01, TMC-CLV-06-01, MDCO-CLV-12-01 (PIONEER , PIP study 1) studies are part of the extrapolation plan of efficacy data from adult patients to the paediatric population from birth to less than 18 years of age.

### 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 September 2028
Deferral for one or more studies contained in the paediatric investigation plan:	Yes

## **Annex II**

### **Information about the authorised medicinal product**

***Information provided by the applicant:***

**Condition(s) and authorised indication(s):**

1. Treatment of hypertensive disease

Authorised indications:

- Cleviprex is indicated for the rapid reduction of blood pressure in the perioperative setting in adults.
  - Invented name(s): Cleviprex and associated names
  - Authorised pharmaceutical form(s): Emulsion for injection
  - Authorised route(s) of administration: Intravenous use
  - Authorised via decentralised procedure