EMADOC-1700519818-2347002

European Medicines Agency decision

EMA/PE/0000246904

of 12 September 2025

on the acceptance of a modification of an agreed paediatric investigation plan for cobolimab 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/0000246904

of 12 September 2025

on the acceptance of a modification of an agreed paediatric investigation plan for cobolimab 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 Union procedures for the authorisation and supervision of medicinal products for human use and establishing a European Medicines Agency[2],

Having regard to the European Medicines Agency's decision P/0480/2023 issued on 1 December 2023,

Having regard to the application submitted by Glaxosmithkline Trading Services Limited on 21 March 2025 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 25 July 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.

(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, as amended.
[2] OJ L 136, 30.4.2004, p. 1, as amended.

Has adopted this decision:

Article 1

Changes to the agreed paediatric investigation plan for cobolimab, 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 Glaxosmithkline Trading Services Limited, 12 Riverwalk, D24 YK11 - Dublin 24 , Ireland.

EMADOC-1700519818-2110801

Amsterdam, 25 July 2025

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

EMA/PE/0000246904

Scope of the application

Active substance(s):

Cobolimab

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of all conditions included in the category of malignant neoplasms including lymphoma (except lung cancers and hematopoietic malignancies)

Pharmaceutical form(s):

Solution for infusion

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

GlaxoSmithKline Trading Services Limited

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, GlaxoSmithKline Trading Services Limited submitted to the European Medicines Agency on 21 March 2025 an application for modification of the agreed paediatric investigation plan with a deferral as set out in the European Medicines Agency's decision P/0480/2023 issued on 1 December 2023.

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

The procedure started on 26 May 2025.

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 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 all conditions included in the category of malignant neoplasms including lymphoma (except lung cancers and hematopoietic malignancies)

2.1.1. Indication(s) targeted by the PIP

Treatment of paediatric patients with a relapsed or refractory or treatment naïve malignancy

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)

Solution for infusion

2.1.4. Measures

Area	Description
Quality-related studies	**Study 1** Development of an age appropriate presentation
Non-clinical studies	Not applicable
Clinical studies	**Study 2** Open-label, single arm, two part trial to determine a recommended phase 2 dose, evaluate pharmacokinetics, pharmacodynamics and safety (part 1) and safety and activity (part 2) of cobolimab in combination with dostarlimab in children from birth to less than 18 years of age (and adults) with a relapsed or refractory solid tumours (part 1), including in part 2, patients with treatment naïve melanoma and relapsed or refractory Hodgkin's lymphoma, to identify the final target population for study 3. **Study 3** Open-label, randomised, active controlled trial to evaluate safety, and efficacy, of cobolimab in combination with dostarlimab compared to best standard of care in a target population identified in study 2.

Modelling and simulation studies	**Study 4** Modelling and simulation study, to support characterisation of pharmacokinetics of cobolimab in combination with dostarlimab in children from birth to less than 18 years of age with solid tumours.
Other studies	Not applicable
Extrapolation plan	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 December 2036
Deferral for one or more measures contained in the paediatric investigation plan:	Yes

Annex II

Information about the authorised medicinal product

Information provided by the applicant:

The product is not authorised anywhere in the European Community.