



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/532192/2023

European Medicines Agency decision P/0497/2023

of 1 December 2023

on the acceptance of a modification of an agreed paediatric investigation plan for glycopyrronium bromide (Axhidrox), (EMEA-002383-PIP01-18-M03) 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 726/2004¹,

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 Agency²,

Having regard to the European Medicines Agency's decision P/0420/2020 issued on 23 October 2020, the decision P/0565/2021 issued on 21 December 2021 and the decision P/0467/2022 issued on 17 November 2022.

Having regard to the application submitted by Dr. August Wolff GmbH & Co. KG – Arzneimittel on 3 August 2023 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 13 October 2023, 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.

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 glycopyrronium bromide (Axxidrox), cream, topical use, 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 Dr. August Wolff GmbH & Co. KG – Arzneimittel, Sudbrackstr. 56, 33611 – Bielefeld, Germany.



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EMA/PDCO/376798/2023 Corr¹
Amsterdam, 10 November 2023

Opinion of the Paediatric Committee on the acceptance of a modification of an agreed Paediatric Investigation Plan EMA-002383-PIP01-18-M03

Scope of the application

Active substance(s):

Glycopyrronium bromide

Invented name and authorisation status:

See Annex II

Condition(s):

Treatment of hyperhidrosis

Pharmaceutical form(s):

Cream

Route(s) of administration:

Topical use

Name/corporate name of the PIP applicant:

Dr. August Wolff GmbH & Co. KG – Arzneimittel

Basis for opinion

Pursuant to Article 22 of Regulation (EC) No 1901/2006 as amended, Dr. August Wolff GmbH & Co. KG – Arzneimittel submitted to the European Medicines Agency on 3 August 2023 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/0420/2020 issued on 23 October 2020, the decision P/0565/2021 issued on 21 December 2021 and the decision P/0467/2022 issued on 17 November 2022.

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

¹ 28 November 2023



The procedure started on 11 September 2023.

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 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 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)

Waiver

1.1. Condition:

Treatment of hyperhidrosis

The waiver applies to:

- the paediatric population from birth to less than 12 years of age;
- cream, topical use;
- on the grounds that clinical studies with the specific medicinal product cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

2. Paediatric investigation plan

2.1. Condition:

Treatment of hyperhidrosis

2.1.1. Indication(s) targeted by the PIP

Treatment of severe primary axillary hyperhidrosis

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

From 12 years to less than 18 years of age

2.1.3. Pharmaceutical form(s)

Cream

2.1.4. Measures

Area	Description
Quality-related studies	Not applicable
Non-clinical studies	Not applicable
Clinical studies	Study 1 (GPBK-08/2018) Open-label, uncontrolled study to evaluate safety, local tolerability, systemic exposure and efficacy of glycopyrronium bromide (GPB) in children from 12 years to less than 18 years of age with hyperhidrosis.
Extrapolation, modelling and simulation studies	Study 2 (GPBK-08/2018-EX) Extrapolation study to evaluate the use of the product in the treatment of hyperhidrosis in children from 12 to less than 18 years of age with hyperhidrosis.

Other studies	Not applicable
Other measures	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 October 2024
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:

Condition(s) and authorised indication(s)

1. Treatment of hyperhidrosis

Authorised indication(s):

- Treatment of hyperhidrosis
 - Invented name(s): Axhidrox
 - Authorised pharmaceutical form(s): cream
 - Authorised route(s) of administration: topical use
 - Authorised via decentralised procedure