EMA/648358/2021

European Medicines Agency decision

P/0435/2021

of 22 November 2021

on the refusal of a product specific waiver for perflubutane (EMEA-003037-PIP01-21) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

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 application submitted by GE Healthcare AS on 1 June 2021 under Article 13 of Regulation (EC) No 1901/2006,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 12 November 2021 in accordance with Article 13 of Regulation (EC) No 1901/2006,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee has given, following a re-examination procedure of the Paediatric Committee's opinion according to Article 25(3) of Regulation (EC) No 1901/2006, an opinion on the refusal of a product specific waiver.

(2) It is therefore appropriate to adopt a decision refusing a waiver.

Has adopted this decision:

Article 1

A waiver for perflubutane, powder and solvent for dispersion for injection, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby refused.

Article 2

This decision is addressed to GE Healthcare AS, Nycoveien 1, NO-0485 – Oslo, Norway.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

EMA/PDCO/603450/2021
Amsterdam, 12 November 2021

Final opinion of the Paediatric Committee on the refusal of a product specific waiver

EMEA-003037-PIP01-21

Scope of the application

Active substance(s):

Perflubutane

Condition(s):

Diagnostic evaluation of focal hepatic lesions

Pharmaceutical form(s):

Powder and solvent for dispersion for injection

Route(s) of administration:

Intravenous use

Name/corporate name of the PIP applicant:

GE Healthcare AS

Basis for opinion

Pursuant to Article 13 of Regulation (EC) No 1901/2006 as amended, GE Healthcare AS submitted for agreement to the European Medicines Agency on 1 June 2021 an application for a product-specific waiver on the grounds set out in Article 11(1) of said Regulation for the above mentioned medicinal product.

An Opinion was adopted by the Paediatric Committee 10 September 2021, recommending the refusal of a waiver for all subsets of the paediatric population and the above mentioned condition(s) for the above mentioned product. GE Healthcare AS received the Paediatric Committee Opinion on 20 September 2021.

GE Healthcare AS submitted written notice including detailed grounds to the European Medicines Agency on 18 October 2021 to request a re-examination of the Opinion.

The re-examination procedure started on 19 October 2021.

A meeting with the Paediatric Committee took place on 10 November 2021.

Final Opinion

1. The Paediatric Committee, having assessed the detailed grounds for the re-examination request in accordance with Article 25(3) of Regulation (EC) No 1901/2006 as amended, maintains its opinion and recommends, as set out in the appended summary report:

   - to refuse the granting of a product-specific waiver for all subsets of the paediatric population and the above mentioned condition(s) as it does not meet the grounds detailed in Article 11(1) of said Regulation.

   The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The scientific conclusions and the grounds for refusal are set out in the summary report appended to this opinion.

3. The grounds for refusal are summarised in 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

Grounds for the refusal of the waiver

1. Waiver

1.1. Condition:

Diagnostic evaluation of focal hepatic lesions

The request for the waiver applied to:

- all subsets of the paediatric population from birth to less than 18 years of age;
- for powder and solvent for dispersion for injection, intravenous use.

The waiver request does not provide evidence to support the following grounds set out in Article 11(1) of Regulation (EC) No 1901/2006 that:

- (a) the specific medicinal product is likely to be ineffective or unsafe in the paediatric population;
- (b) the disease or condition for which the specific medicinal product is intended occurs only in adult populations;
- (c) the specific medicinal product does not represent a significant therapeutic benefit over existing treatments for paediatric patients.

Because:

- the PDCO disagreed with the applicant(s)' argumentation that the specific medicinal product is likely to be ineffective or unsafe;
- the disease or condition for which the specific medicinal product is intended, does occur in the paediatric population(s);
- measures would be justified by the expected therapeutic benefit and clinical trials may be feasible;
- the specific medicinal product may represent a significant therapeutic benefit as the needs are not met;
- clinical studies may fulfil a therapeutic need of the paediatric population.

The waiver request is therefore refused by the PDCO.