EMADOC-1700519818-2008871
Human Medicines Division

Summary report

EMA/PDCO review of a class waiver

Class waiver

Case number: EMA/GE/0000254753

Condition: Diagnosis of IgE-mediated allergy

Official address Domenico Scarlattilaan 6 ● 1083 HS Amsterdam ● The Netherlands
Address for visits and deliveries Refer to www.ema.europa.eu/how-to-find-us
Send us a question Go to www.ema.europa.eu/contact **Telephone** +31 (0)88 781 6000

Administrative and procedure information

Start of procedure	22 April 2025
First discussion by the PDCO	23 May 2025
Adoption of the PDCO Opinion	23 May 2025

Therapeutic class or condition concerned by the class waiver:

Diagnosis of IgE-mediated allergy

EMA Decision number granting the class waiver and Date:

CW/0001/2015 of 23 July 2015

Initial ground:

Clinical studies with diagnostic allergens cannot be expected to be of significant therapeutic benefit to or fulfil a therapeutic need of the specified paediatric subset(s).

Scientific justification for the review or revocation the granted class waiver:

Comment:

EMA Scientific Officer:

The proposed condition to be covered by a class waiver is 'Diagnosis of IgE-mediated allergy'.

Clinical studies with medicinal products, intended to diagnose IgE-mediated allergy, are not expected to bring a significant therapeutic benefit to or to fulfil a therapeutic need of the paediatric population. This is because sensitivity and specificity of diagnostic allergens can be extrapolated from adults to children.

This will avoid unnecessary trials in the paediatric population.

PDCO Rapporteur:

The argumentation of the EMA Scientific Officer is completely endorsed.

Even if different doses/concentrations would be used in the paediatric population / in justified cases (e.g. for a Skin Prick Test, SPT procedure), this is also a common procedure that is used for severe allergic adult patients, where for instances lower concentrations are used for safety reasons.

The preferred site for SPT in the paediatric population might be different for practical reasons. Usually it is applied on the volar surface of the forearm, but in infants, the back is the preferred site for space reasons. However, the different application site has little or no effect on concentration or safety of the products.

Bibliographic references:

1. Bousquet J. et al., 2012. Practical guide to skin prick tests in allergy to aeroallergens. Position paper EAACI. Allergy, 67(1), pp. 18-24. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1111/j.1398-9995.2011.02728.x [Accessed May 20, 2025].
2. Ansotegui I. J. et al., 2020. IgE allergy diagnostics and other relevant tests in allergy, a World Allergy Organization position paper. World Allergy Organ J., 13(2):100080. Available at: https://doi.org/10.1016/j.waojou.2019.100080 [Accessed May 20, 2025].
3. Heinzerling L. et. al. 2013 The skin prick test - European standards. Clin Transl Allergy. 2013 3(1), p.3. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1186/2045-7022-3-3 [Accessed May 20, 2025].
4. Riggioni C. et al., 2023 .Systematic review and meta-analyses on the accuracy of diagnostic tests for IgE-mediated food allergy. Allergy. 2024;79(2), pp. 324-352. Available at: https://onlinelibrary.wiley.com/doi/epdf/10.1111/all.15939 [Accessed May 20, 2025].

Paediatric Committee Discussion:

The PDCO considered that sensitivity and specificity of diagnostic allergens can be extrapolated from adults to children. This will avoid unnecessary trials in the paediatric population.

The Committee recommends granting a class-waiver for all medicinal products in the condition 'Diagnosis of IgE-mediated allergy' 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).

Paediatric Committee Opinion and Grounds:

In May 2025, the PDCO adopted a positive opinion to recommend updating the list of classes of medicines covered by a class waiver.

The Committee recommends granting a class-waiver for all medicinal products in the condition 'Diagnosis of IgE-mediated allergy' 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).