



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

25 June 2026  
EMADOC-1700519818-3253464  
Committee for Medicinal Products for Human Use (CHMP)

## Summary of opinion<sup>1</sup> (post authorisation)

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### Leqvio inclisiran

On 25 June 2026, the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a change to the terms of the marketing authorisation for the medicinal product Leqvio. The marketing authorisation holder for this medicinal product is Novartis Europharm Limited.

The CHMP adopted an extension to the existing indication as follows:<sup>2</sup>

Leqvio is indicated in adults with primary hypercholesterolaemia (heterozygous familial and non-familial) or mixed dyslipidaemia, as an adjunct to diet, **and in paediatric patients aged 12 years and older with heterozygous familial hypercholesterolaemia (HeFH):**

- in combination with a statin or statin with other lipid-lowering therapies in patients unable to reach LDL-C goals with the maximum tolerated dose of a statin, or
- alone or in combination with other lipid-lowering therapies in patients who are statin-intolerant, or for whom a statin is contraindicated.

Detailed recommendations for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published on the EMA website in all official European Union languages after a decision on this change to the marketing authorisation has been granted by the European Commission.

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<sup>1</sup> Summary of positive opinion are published without prejudice to the Commission decision, which will normally be issued 67 days from adoption of the opinion.

<sup>2</sup> New text in bold.

