# Leqvio

## Procedural steps taken and scientific information after the authorisation*

*Due to the Agency`s update of its procedure management systems, an additional document, reflecting the historical lifecycle may be available in the 'Assessment history' section. For the complete product lifecycle procedures, you may need to also refer to **EPAR - Procedural steps taken and scientific information after authorisation (archive)**.

| Application number | Scope | Opinion/ Notification [1] issued on | Commission Decision Issued[2] / amended on | Product Information affected[3] | Summary |
|---|---|---|---|---|---|
| EMA/R/0000247528 | Renewal of marketing authorisation. | 22/05/2025 | 30/07/2025 | Annex II and PL | Based on the review of data on quality, safety, and efficacy, the CHMP considered that the benefit-risk |

[1] Notifications are issued for type I variations and Article 61(3) notifications (unless part of a group including a type II variation or extension application or a worksharing application). Opinions are issued for all other procedures.
[2] A Commission decision (CD) is issued for procedures that affect the terms of the marketing authorisation (e.g. summary of product characteristics, annex II, labelling, package leaflet). The CD is issued within two months of the opinion for variations falling under the scope of Article 23.1a(a) of Regulation (EU) No. 712/2012, or within one year for other procedures.
[3] SmPC (Summary of Product Characteristics), Annex II, Labelling, PL (Package Leaflet).

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| | | | | | balance of Leqvio in the approved indication remains favourable and therefore recommended the renewal of the marketing authorisation with unlimited validity. |
| PSUR / EMA/PSUR/0000257862 | Periodic Safety Update EU Single assessment - inclisiran | 10/07/2025 | n/a | n/a | PRAC recommendation - maintenance |