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Novartis’s Leqvio delay could last a year

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Novartis’s Leqvio was supposed to have been one of the big approvals of 2020. The way things are going the project, known generically as inclisiran, will be lucky if it gets the US nod before 2022. Novartis says it expects a response to last year’s FDA complete response letter to be submitted by the second or third quarter of this year, dashing any hopes of a quick resolution. The group’s chief executive, Vas Narasimhan, noted during today’s fourth-quarter earnings call that the exact timing depended on the third-party manufacturer that runs the facility the FDA was unable to inspect owing to Covid-19 travel restrictions, which ultimately led to the CRL. It will be up to the agency whether it wants an in-person inspection, he added. The news is another blow to Novartis’s business development team: the Swiss company gained Leqvio, a siRNA therapy targeting PCSK9, via its $9.7bn acquisition of The Medicines Company in 2019. Mr Narasimhan tried to put a positive spin on the news, saying it meant Novartis would be better prepared to launch Leqvio, hopefully without the complications of the Covid-19 pandemic. But sales forecasts, for the next couple of years at least, are now under threat.

This article has been changed to clarify Leqvio's mechanism of action.