Comparing the Time to Reimbursement of the Orphan Drug Evrysdi in Türkiye Versus EURO-5 Markets

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Objectives

Access to orphan drugs varies considerably across Europe due to differences in pricing and reimbursement processes. Reimbursement timelines in Türkiye are generally longer compared to the EURO-5 markets—France, Germany, Italy, Spain and the UK—thus delaying patient access. Spinal muscular atrophy (SMA) is a rare disease with a high prevalence in Türkiye, where only two innovative treatments are registered. The primary objective of this analysis is to compare the time to reimbursement of Roche's (Switzerland) orphan drug Evrysdi (risdiplam) in Türkiye versus the EURO-5 markets and to draw implications for patient access to rare disease therapies.

Methods

The marketing authorization and first reimbursement dates of Evrysdi 0.75mg/mL (80mL) in the EURO-5 markets were extracted from GlobalData's POLI database. For Türkiye, the marketing authorization date was extracted from the Turkish Medicines and Medical Devices Agency's (TITCK) official list of registered products and the first reimbursement date from the Social Security Institution's (SGK) Health Implementation Communique, dated April 26, 2025. The period (in days) between the marketing authorization date and the official national reimbursement decision by the respective authority (SGK for Türkiye, HAS for France, G-BA for Germany, AIFA for Italy, CIPMA for Spain, and NICE for the UK) was used to calculate time to reimbursement.

Results

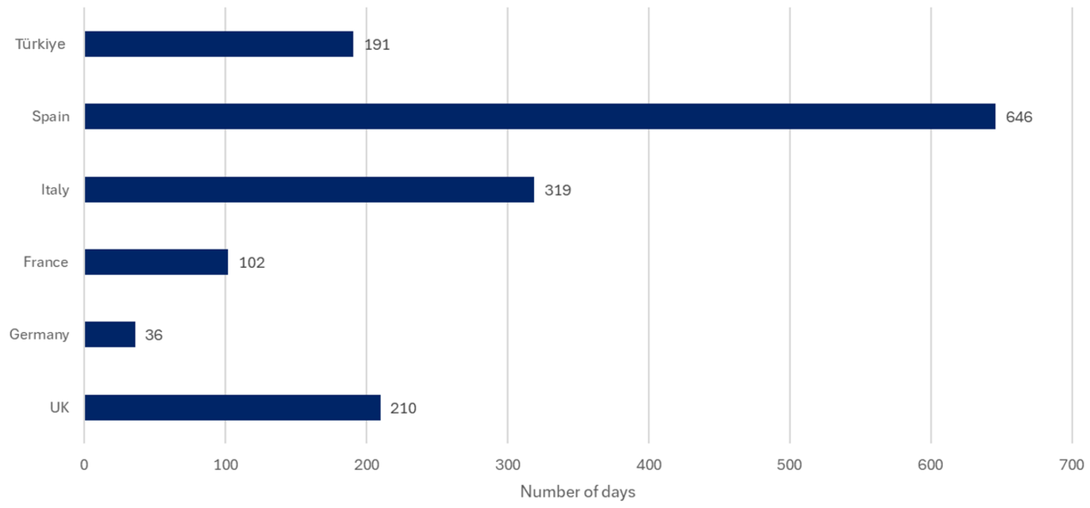
France, Germany, Türkiye, and the UK all introduced Evrysdi through early access schemes, such as compassionate use programs, before marketing authorization and reimbursement were granted. The marketing authorization, reimbursement, and launch dates across the six markets are presented in the table below.

Key dates for Evrysdi

Marketing authorization, reimbursement, and launch dates of Evrysdi			
Country	**Marketing authorization date**	**First reimbursement date**	**Launch date**
France	March 26, 2021	July 6, 2021	July 6, 2021
Germany	March 26, 2021	May 1, 2021	May 1, 2021
Italy	March 26, 2021	February 8, 2022	July 26, 2021
Spain	March 26, 2021	January 1, 2023	January 10, 2023
Türkiye	October 18, 2024	April 26, 2025	N/A
UK	May 20, 2021	December 16, 2021	June 21, 2021

The European Commission granted marketing authorization to Evrysdi on March 30, 2021, while the TITCK registered the therapy on October 18, 2024, indicating a three-year delay in approval in Türkiye.

Average time to reimbursement of Evrysdi in Türkiye vs. EURO-5



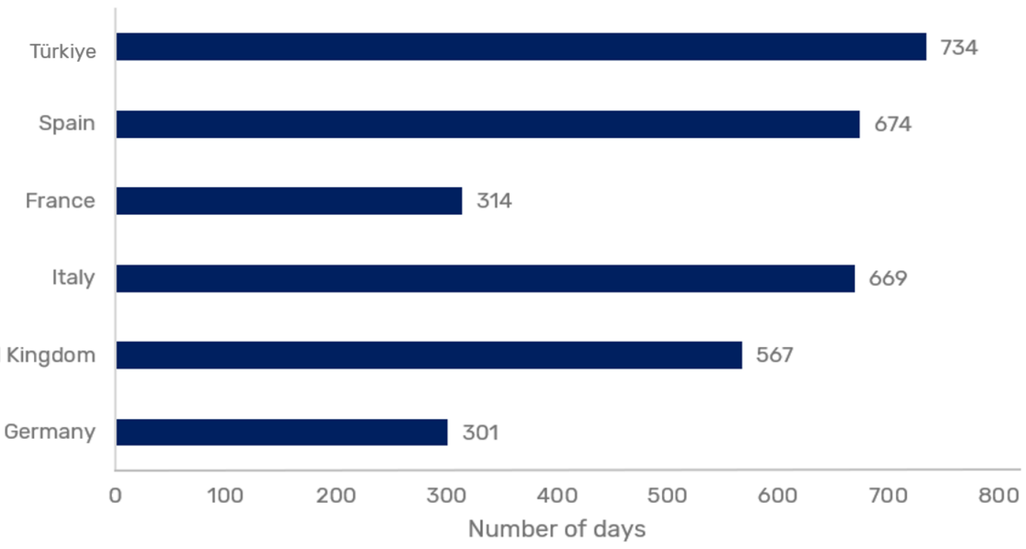
Across the six markets, the time to reimbursement ranged from 36 to 646 days.

Germany was the first country in this analysis to grant reimbursement to Evrysdi, 36 days after initial EC approval. Under Germany's reimbursement scheme, innovative medicines are granted reimbursement upon entry into the German market. Additionally, newly approved orphan drugs are presumed to demonstrate a positive "added benefit" at the time of EU marketing authorization and are thus not required to undergo a full benefit assessment, hence expediting their market access.

France was next with a time to reimbursement of 102 days, followed by Türkiye (191 days), the UK (210 days), Italy (319 days), and Spain (646 days). Notably, despite its later approval date for Evrysdi, Türkiye overtook three EURO-5 markets in time to reimbursement, even in the absence of specific legislation for orphan drugs, indicating its growing prioritization of orphan drugs in reimbursement. Spain is the only country in this analysis that did not introduce Evrysdi through a special access scheme prior to approval, and the Spanish Ministry of Health (MoH) only granted unrestricted access and reimbursement under the public health system following a campaign led by the SMA patient association FundAME—hence, the longer time to reimbursement in this country.

The reimbursement timeline for Evrysdi is notably different from the one for all branded drugs. Türkiye takes the longest average time to grant reimbursement for branded drugs, followed by Spain and Italy, while Germany and France have the shortest timelines.

Time to reimbursement of all branded drugs, 2024



Conclusions

These observations suggest that Evrysdi not only experienced delayed market entry by almost three years, but also late reimbursement in Türkiye compared to the EURO-5 markets. This is mainly due to the absence of orphan drug–specific legislation and the SGK's strict criteria for the reimbursement of high-cost therapies. In 2023, Türkiye's MoH introduced a new framework to guide reimbursement decisions for orphan drugs. The guidance document places emphasis on value-based reimbursement decisions, but as of 2025, Türkiye's SGK introduced stricter regulations, including more frequent use of pharmacoeconomic assessments to guide reimbursement decisions for orphan drugs, among others. Currently, there are only two innovative SMA therapies on the SGK's reimbursement list: Spinraza (nusinersen) and Evrysdi, with Zolgensma (onasemnogene abeparvovec) still under dispute due its $2.1 million price tag. However, the SGK's established criteria and conditions for their reimbursement indicate that only a small number of SMA patients will have access to these treatments. Despite this, the quicker time to reimbursement in Türkiye than three top EU markets is a sign that orphan drugs are being prioritized for reimbursement to improve patient access.