# An evaluation of orphan medicine access in Ireland

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## Objectives

The aim of this research is to evaluate the level of access to rare disease medicines in Ireland and examine how the country compares to other EU member states with similar health status and socio-economic conditions.

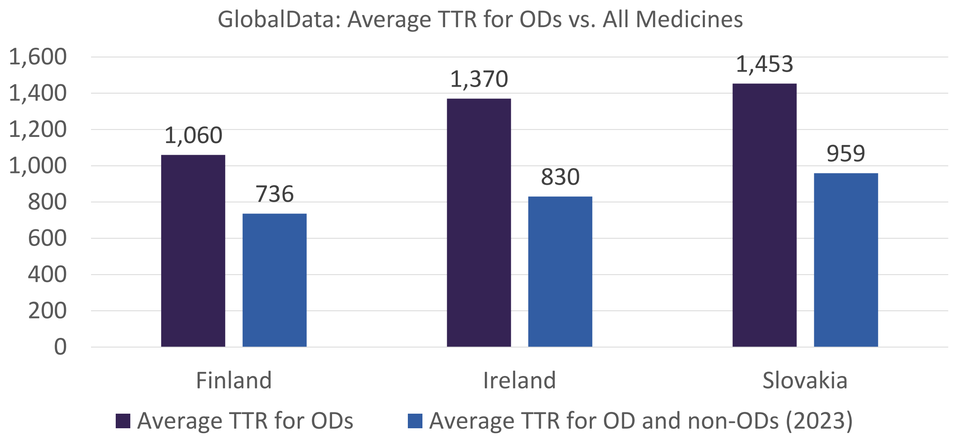
## Methods

All medicines with EU marketing authorization approval (MAA) that are listed as orphan drugs (OD) by the EMA were identified from the Community Register of Orphan Medicinal Products. Information for the same drugs was extracted from GlobalData's pricing and reimbursement database POLI for Ireland, Finland and Slovakia. For each OD, the following data was generated and subject to a cross-country analysis: reimbursement status, therapeutic area, time to reimbursement, and first reimbursement date.

## Results

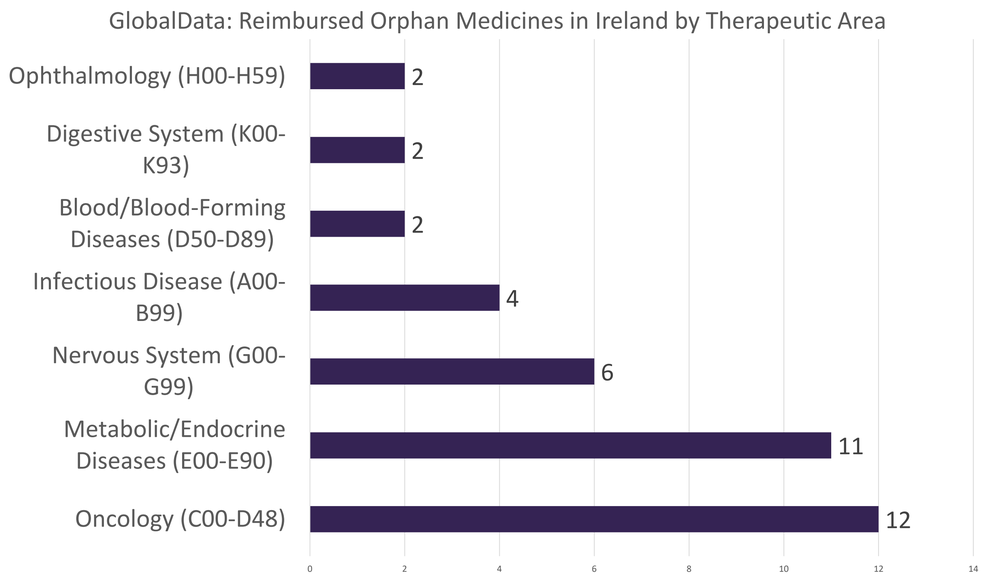
A total of 152 medicines with MAA in the EU-27 have orphan status as of June 2024. 39 rare disease medicines (25.6%) were available for reimbursement in Ireland. Of these, 30 products (76.9%) have general reimbursement status; 9 (23.1%) were available through managed access protocols (MAPs). In addition, POLI data indicates that 3 products previously held reimbursement. But that status was subsequently withdrawn.

The average time to reimbursement (TTR) from the date of MAA is estimated at 1,370 days (minimum 41/maximum 4,365 days). Ireland's average TTR for orphan and non-orphan drugs was 830 days in 2023, according to POLI.




For Health Service Executive (HSE) MAP ODs – involving a confidential price discount in exchange for limited prescription access on a named-patient basis – the average TTR amounted to 1,968 days (n=8/9). A MAP therefore adds an average of 598 days to the OD reimbursement process.

### *Reimbursed ODs in Ireland by Therapeutic Area*



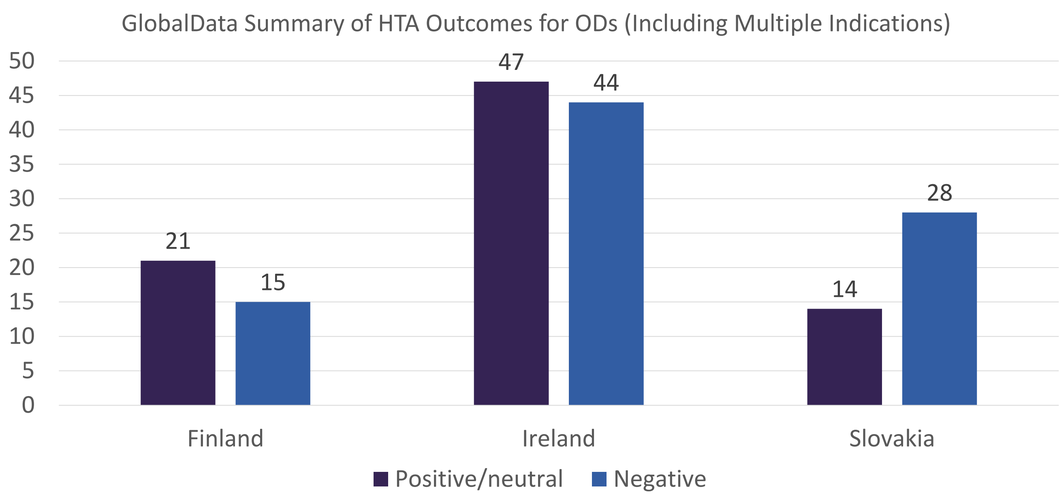

31% of reimbursed ODs are in the oncology therapeutic area, followed by metabolic and endocrine diseases (28%) and nervous system diseases (15%).

33% of MAP ODs are in the metabolic and endocrine disease therapeutic area, followed by digestive system and blood/blood-forming diseases (22% each), while nervous system and ophthalmology account for 11% each.

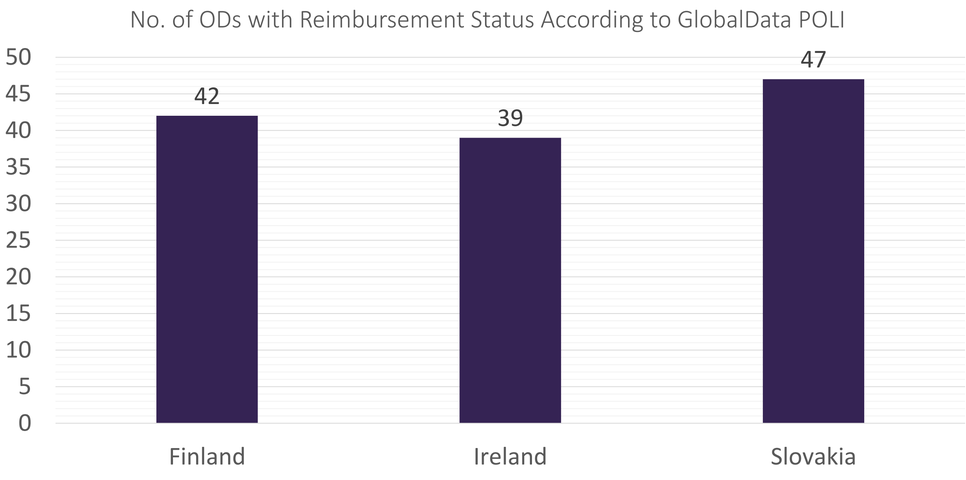
### *Cross Country Comparison with Finland and Slovakia*

GlobalData conducted a three-way cross-country comparison of reimbursement trends in Finland, Ireland, and Slovakia – Eurozone countries which share similar population sizes but with Ireland having a much higher modified gross national income (GNI) per capita.

### *Positive HTA Outcomes for ODs Are More Common in Ireland*




### *Yet Ireland Ranks Below Finland & Slovakia for Reimbursed ODs*




### *Is Ireland starting to turn a corner?*

Ireland's performance on reimbursement appears to be improving when compared to Finland, but not when compared against Slovakia: 7 rare disease drugs, with OD status in POLI, were reimbursed in the first 10 months of 2024 in Ireland compared to 10 in Slovakia and 3 in Finland.

While there is no hardwired funding mechanism for ODs, the government allocated EUR30 million ($37 million) in 2025 to broaden HSE access to new medicines (covering newly launched innovative medicines and ODs).

Ireland does not operate an early access to medicine scheme or have a separate HTA evaluation process that is specifically tailored to ODs. However, these issues may be addressed in a future national rare disease strategy, a consultation process for which was launched by the Department of Health in July 2024. A strategy document outlining potential reform areas is expected to be published in early 2025.

Alternatively, negotiations between the HSE and Irish Pharmaceutical Healthcare Association (IPHA) over a new four-year pricing and supply agreement for innovative medicines in 2025 may address OD access.

## Conclusions

There is a relative low availability of ODs for rare diseases in Ireland. A quarter of ODs are reimbursed, and patients wait an average of 45 months after the date of MAA to obtain reimbursement access. POLI data points to a slight improvement in 2024, with the number of new ODs reimbursed reaching 7 as of September, with an average TTR of 1,367 days (minimum 220/maximum 2,017 days). For comparison, the number of ODs reimbursed in all of 2023 was 6, with an average TTR of 1,326 days (minimum 433/maximum 2,966 days). Eight new ODs were reimbursed in 2022, with an average TTR of 1,626 days (minimum 41/maximum 3,758 days).