Health technology assessment (HTA) systems and risk identification strategies: a comparative analysis across western European countries, Canada, and Australia

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Highlights

- IQVIA was commissioned by the Dutch National Health Care Institute (Zorginstituut Nederland) to conduct research across 10 European countries and 2 non-European countries, systematically mapping how each nation organizes its reimbursement systems for medicines. For each country, the study inventoried the structure of reimbursement systems, the allocation of roles and responsibilities, the use of (international) horizon scanning, and the execution of risk analyses. Additionally, IQVIA performed an in-depth analysis of three countries with distinctive features.
- The overall conclusion is that the Netherlands is at the forefront in implementing risk analyses and management measures, such as the use of the lock (‘sluis’) for expensive medicines. Surrounding countries are also adopting interesting management measures, but none have yet made the transition to the future HTA system (TSG) envisioned by the Netherlands.
- These insights highlight opportunities for the Netherlands to further innovate and lead in risk-based reimbursement strategies, while providing valuable lessons for international best practices.

Background

- The Dutch Ministry of Health (VWS) has initiated a comprehensive action plan to reform the national reimbursement system for medicines (TSG, ‘toekomstbestendig stelsel geneesmiddelen’), aiming to ensure timely access to appropriate therapies at a socially acceptable cost. This plan is structured into five distinct phases: improved horizon scanning, risk identification, rapid review and triage, risk mitigation, and cyclical reassessment.[1]
- To support this reform, the Dutch National Health Care Institute (Zorginstituut Nederland) was commissioned to conduct an international exploration of risk assessment practices in the reimbursement processes for medicines.[2]

Objective

This study aimed to describe and analyze health technology assessment (HTA) systems in other countries to understand the risk identification strategies and reimbursement pathways utilized, intended to inform the potential HTA system reformations in the Netherlands.

Methods

This study was carried out in two steps:

1. The initial phase of this analysis entailed describing the HTA systems of twelve countries (the Netherlands, Belgium, France, Spain, Germany, Italy, Norway, Sweden, United Kingdom, Ireland, Canada, and Australia) **(Figure 1).**
2. A more detailed analysis was subsequently conducted for Ireland, Norway, and Canada, focusing on risk identification strategies, methods for risk assessment, utilization of horizon scanning, types and criteria for risks, and the integration of risk analyses into the HTA process.

The assessments were based on a desk research using publicly available information. Interviews with HTA experts from IQVIA in respective countries were conducted to confirm the assessment reports.

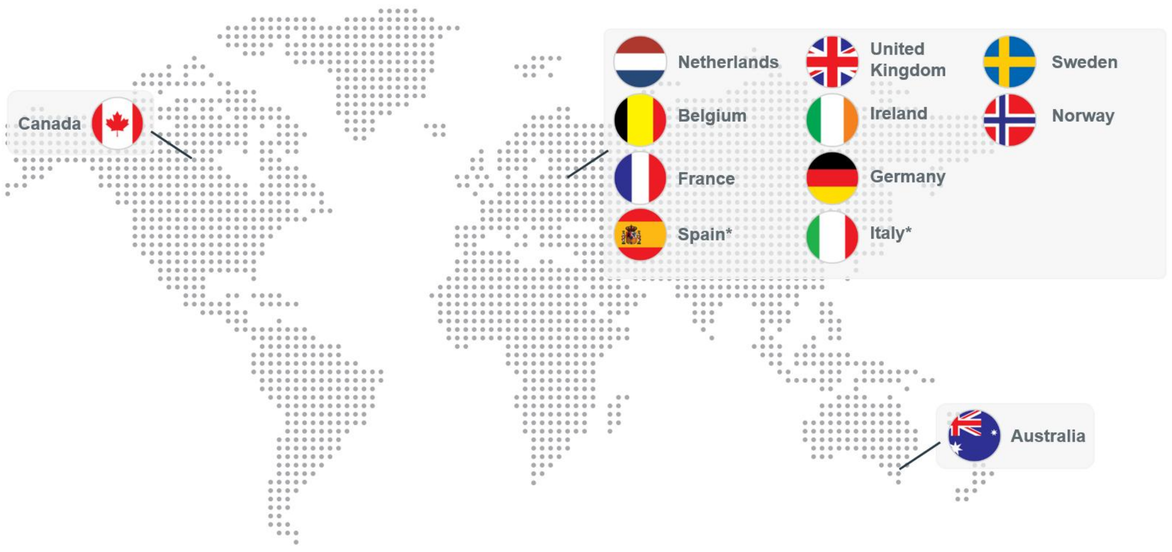


Figure 1: Countries in scope for this project aimed at describing the risk identification strategies of various HTA systems. *The reimbursement process in Spain underwent reformations at the time of the assessment. Whereas the autonomous regions used to individually assess whether a medicine qualifies for reimbursement, the reformations will likely result into a national assessment. For this reason, it was decided not to further elaborate on the reimbursement procedure in Spain. The reimbursement process in Italy was reformed at the beginning of 2024, but there was still much uncertainty about the new procedures. The old assessment system was therefore used for the current analysis.

Results

Phase 1

- In half of the included countries (6 out of 12) a single authority is responsible for the HTA, while multiple authorities are involved in the remaining countries.
- Most countries (67%; 8 out of 12) incorporate horizon scanning into their HTA processes, though the purpose and implementation of horizon scanning varies widely.
- Only four countries (the Netherlands, Norway, Sweden, and Ireland) employ specific risk identification strategies to guide reimbursement procedures for specific therapies **(Figure 2).** Most other countries rely on broader criteria such as effectiveness, innovation, or disease burden. Most countries do have specific procedures for certain therapies such as innovative medicines or orphan drugs.

	NLD	BEL	FRA	ESP	DEU	ITA	NOR	SWE	GBR	IRL	CAN	AUS
Risk identification*	✓	✗	✗	-	✗	✗	✓	✓	✗	✓	✗	✗
Horizon scanning**	✓	✗	✓	-	✗	✓	✓	✓	✓	✓	✓	✗

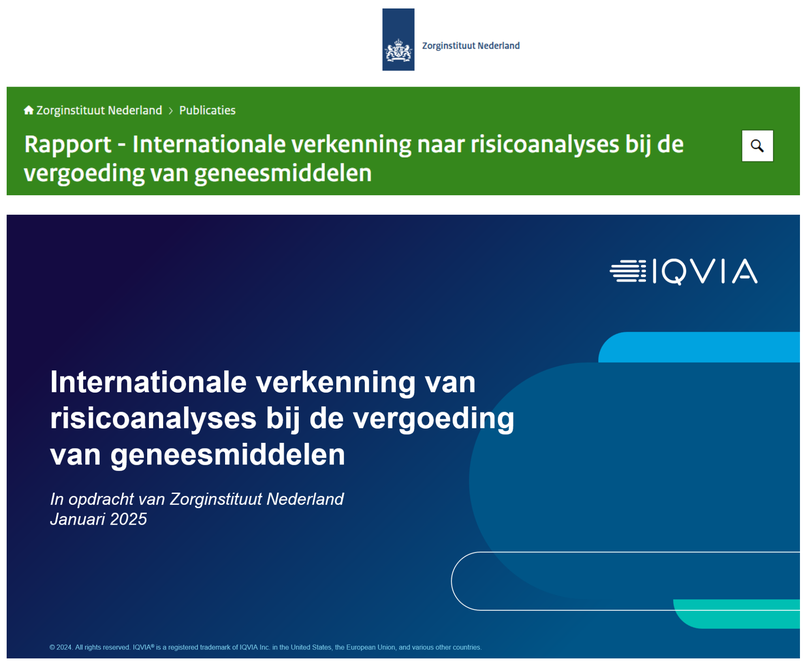
Figure 2: Overview of countries applying risk identification strategies and horizon scanning as part of their HTA system.
*Countries where choices regarding the reimbursement procedure are made based on financial or other risks are marked with a ✓. Countries where all medicines are assessed, and where different procedures exist only based on the characteristics of the medicines, are marked with a ✗.
**Countries that use a horizon scan (national or international), regardless of its purpose, are marked with a ✓. Countries that do not manage or use a horizon scan are marked with a ✗.

Phase 2

- Ireland: All medicines undergo a rapid review to determine whether a full HTA is required. This selective approach allows some medicines to be reimbursed more quickly. There are no separate procedures for specific categories of medicines.
- Canada: Specific procedures exist for certain categories of medicines, such as oncology drugs. All medicines are assessed nationally, but after national negotiations, provinces retain autonomy to decide on reimbursement.
- Norway: There are three distinct systems for medicine reimbursement: specialist care (H-prescriptions), essential primary care (blue prescriptions), and other medicines (white prescriptions). Each system has its own assessment procedures.

Comparison to the Netherlands

- The Netherlands stands out for its clear and normative criteria dictating the HTA procedure, with decisions based on financial risks prior to the assessment. Other countries utilize other criteria, including relative effectiveness, innovation, and disease burden, as risk identification strategies.
- Compared to the Netherlands, foreign reimbursement processes tend to be more flexible after the procedure has started. For example, in Ireland, medicines can be reimbursed without a full assessment if suitable price agreements are reached, and Norway offers multiple assessment routes for inpatient medicines.
- Several countries, like the Netherlands, have different reimbursement routes for inpatient (intramural) and outpatient (extramural) medicines. In many countries, a national institute plays an advisory role, but assessments may also be conducted by local or regional authorities.
- The Netherlands is one of the few countries with clear, normative criteria (e.g., budget impact, interchangeability) that determine the assessment pathway. Decisions are made based on financial risks before the assessment begins. Other countries use additional criteria (e.g., effectiveness, innovation, and disease burden) to guide which procedures must be followed.



You can download the complete report by scanning the QR code above[3]

Future implications

The findings from this research provide essential input for the ongoing exploration and potential reformation of the Dutch reimbursement system, offering comparative insights into international best practices for risk identification and management within health technology assessment (HTA) frameworks.

References

1. Ministry of Health of the Netherlands (VWS) (2023). Naar een toekomstbestendig stelsel voor de vergoedings van nieuwe dure geneesmiddelen uit het basispakket.
2. Dutch National Health Care Institute (2025). Advies – Toekomstbestendig stelsel geneesmiddelen.
3. Dutch National Health Care Institute (2025). Rapport – Internationale verkenning naar risicoanalyses bij de vergoeding van geneesmiddelen.

Disclosures

IQVIA was commissioned by the Dutch National Health Care Institute (Zorginstituut Nederland) to carry out this project. MvW, JRM, and PP were employees of IQVIA at the time of project execution. LH and RD were employees of Zorginstituut Nederland at the time of project execution.

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