



Review of HTA Outcomes and Timelines in Australia, Canada, Europe, and the UK 2021-2025

CIRS HTADock Project | R&D Briefing 107

Introduction

In 2017, CIRS launched the [HTADock project](#) as part of its health technology assessment (HTA) programme. This project explores the synchronisation between the regulatory and HTA landscapes, aiming to increase the transparency of the outcomes and timelines of HTA assessments. It also seeks to facilitate the enhancement of performance within HTA agencies.

This HTADock briefing analyses publicly available data on new active substances (NASs) reviewed from 2021 to 2025 by key international HTA agencies, each with unique perspectives and methodologies. The agencies involved in this comprehensive study include:

1. Australian Pharmaceutical Benefits Advisory Committee (PBAC)
2. Canada's Drug Agency (CDA-AMC)
3. Institut national d'excellence en santé et en services sociaux (INESSS)
4. English National Institute for Health and Care Excellence (NICE)
5. French Haute Autorité de Santé (HAS)
6. German Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)
7. Irish National Centre for Pharmacoeconomics (NCPE)
8. Zorginstituut Nederland (ZIN)
9. Polish Agencja Oceny Technologii Medycznych i Taryfikacji (AOTMiT)
10. Portuguese Autoridade Nacional do Medicamento e Produtos de Saúde (INFARMED)
11. Scottish Medicines Consortium (SMC)
12. Swedish Tandvårds & läkemedelsförmånsverket (TLV).

The insights derived from this research form an essential component of CIRS's ongoing commitment to advancing regulatory and HTA policies and processes.

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HTADock Methodology

The data on individual NASs reviewed by HTA agencies between 2021 and 2025 were systematically collected from the respective agencies' official websites. Only the **first HTA recommendation**, derived from the initial assessment, was included in the analysis, unless specified. The next figures describe the research methodology, designed to enable robust benchmarking between agencies.

First HTA outcomes: Trichotomous categories

	Positive	Positive with restrictions	Implication for “positive” or “positive with restrictions”	Negative
	List	List with conditions	Listing in the Pharmaceutical Benefits Scheme	Do not list
	Reimburse	Reimburse with conditions	Recommendation for reimbursement	Do not reimburse
	Inscription	Inscription - Avec conditions / Refus d'inscription - Ensemble des aspects	Recommendation for reimbursement	Refus d'inscription - Valeur thérapeutique
	Recommended	Recommended + restrictions	NHS Implementation of NICE guidance	Not recommended
	Majeur/Important	Modéré ou faible	The NHI defines the reimbursement rate accordingly	Insufficient
	Considerable/Major added benefit	Minor/non-quantifiable added benefit	G-BA makes the binding resolution based on benefit assessment	Added benefit not proven/less benefit
	NAS is considered for reimbursement	NAS is considered for reimbursement with conditions	The HSE considers the NCPE outcomes and make decisions on reimbursement.	NAS not recommended for reimbursement
	To include	To include + restrictions	Recommendation for inclusion in the national health system	Not to include
	Prezes Agencji rekomenduje	Prezes Agencji rekomenduje+restrictions	Agency’s president’s recommendation	Prezes Agencji nie rekomenduje
	Deferido	Deferido + restrições	The MoH decides on reimbursement based on the Infarmed report	Indeferido
	Accepted for use within NHS Scotland	Accepted for restricted use within NHS Scotland	Accepted for use within NHS Scotland	Not recommended for use within NHS Scotland
	Ngã i läkemedelsförmånerna	Begränsningar	Include in pharmaceutical benefits scheme	Avslår

Note: The terminology used here is based on the individual agency’s guidance on the official website. **Green** outline indicates that drug reimbursement is possible while **red** outline indicates that drug reimbursement is not possible. A NAS is categorised as Multiple where a single marketing authorisation receives more than one first HTA recommendation on the same day, covering different sub-indications, and the outcomes differ.

HTADock Methodology (Cont.)

Regulatory and HTA process

	Regulatory submission	Regulatory approval	HTA submission	HTA Recommendation
Australia	Submission to TGA	Approval by TGA	17 weeks before PBAC meeting	Month of PBAC meeting in Public Summary Document
Canada (CDA-AMC)	Submission to Health Canada	Approval by Health Canada	Submission provided by CDA-AMC	Final recommendation issued to sponsor and drug plans
Canada (INESSS)	Submission to Health Canada	Approval by Health Canada	Submission provided by INESSS	Opinion transmitted to the minister
England	Submission to MHRA/EMA (ECDRP/IRP)/FDA (IRP)	Approval issued by MHRA	Company evidence submission date	Technology appraisal guidance publication
France	Submission to EMA	Approval issued by EU Commission	Date de validation administrative	Publication of Commission de la transparence review
Germany	Submission to EMA	Approval issued by EU Commission	Date of commission at IQWiG	Publication of the dossier assessment
Ireland	Submission to EMA	Approval issued by EU Commission	Rapid review commissioned	Rapid Review completed/ NCPE (full) assessment completed
Netherlands	Submission to EMA	Approval issued by EU Commission	Letter dated by Minister of health to ZIN	Date of Summary of recommendation by ZIN
Poland	Submission to EMA	Approval issued by EU Commission	Order of the Minister of Health publication	Publication of the President's Recommendation
Portugal	Submission to EMA	Approval issued by EU Commission	Not available in the public domain	Date of the first decision
Scotland	Submission to MHRA/EMA (ECDRP/IRP)/FDA (IRP)	Approval issued by MHRA	Submission provided by SMC	The first statement of advice by SMC
Sweden	Submission to EMA	Approval issued by EU Commission	Submission provided by TLV	Publication of the first released report by TLV

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Key Findings of R&D Briefing 107



In 2025, Germany published the highest number of 1st HTA recommendations across the studied jurisdictions and CDA-AMC presented the lowest proportion of negative HTA outcomes

(Figure 1).



Australia presented the shortest median rollout time from regulatory submission to HTA recommendation in 2025, followed by CDA-AMC (Canada) (Figure 3), which could potentially be attributed to their parallel regulatory/HTA processes. Germany had the highest consistency in rollout times from 2021 to 2025 (Figure 3).



Companies' submission strategies varied across jurisdictions: while countries like Australia, Canada, England, France, and Germany received more than 60% of their HTA submissions less than 3 months after regulatory approval, others such as the Netherlands and Poland often experienced longer delays (Figure 7).



The top four therapeutic areas (alimentary tract and metabolism, blood and blood forming organs, anti-infectives for systemic use, and anti-cancer and immunomodulating agents) made up 66% (199/300) of the unique products assessed by HTA in at least one country between 2021-2025. Anti-cancer and immunomodulators made up 64% (127/199) of the top therapeutic areas (Figure 11).



In all jurisdictions, except for England, Scotland, and Sweden, the median overall time from regulatory submission to HTA recommendation was shorter for products undergoing an expedited review compared to those following the non-expedited review process (Figure 13).



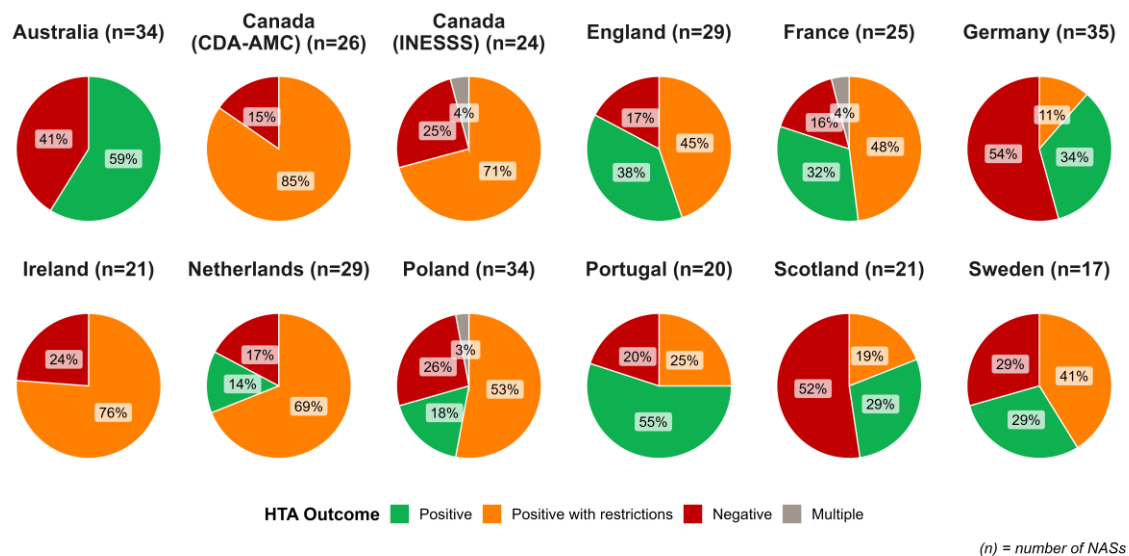
The share of NASs applying for Early Access with HAS fell from 67% in 2022 to 45% in 2024 before rebounding to 64% in 2025. Among applications received, the proportion denied rose from 14% in 2022 to 61% in 2024, remaining at 56% in 2025, suggesting a marked tightening of eligibility criteria from 2024 (Figure 30).



Between 2021 and 2025, 10 NASs received a 1st HTA recommendation in all 12 studied jurisdictions. These NASs often received different HTA outcomes across different jurisdictions, suggesting potential disparities in patient access to new treatments. Additionally, the chronological order of HTA outcomes varied across jurisdictions, potentially influenced by companies' submission strategies and regulatory and HTA review times (Figure 32)

Overview of New Drug Outcomes

Figure 1. First HTA Recommendation for NASs Across Key Jurisdictions (HTA Recommendations in 2025)



Note 1: Please note that some countries may include price negotiation as part of their HTA process

Note 2: Percentages may not sum to 100% due to rounding

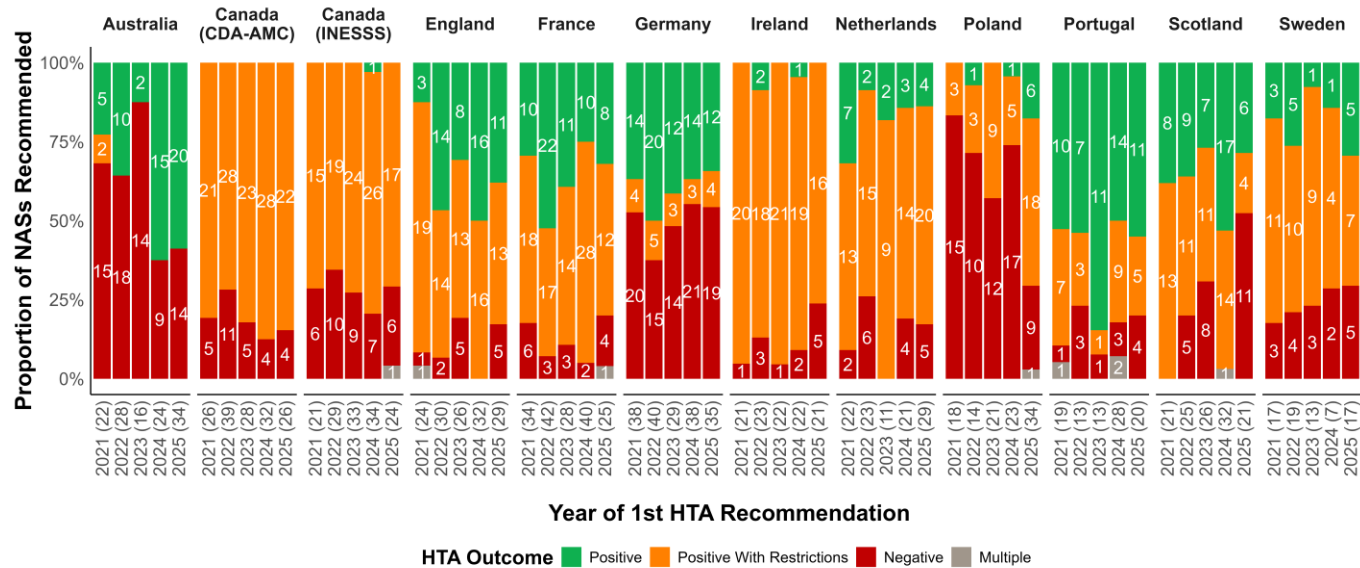
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Germany published the highest number of HTA outcomes for NASs across the studied jurisdictions in 2025.

In 2025, Germany reviewed the highest number of NASs (n=35), followed by Australia and Poland (n=34) (Figure 1). Among these, CDA-AMC presented the lowest proportion of negative HTA outcomes for NASs reviewed by HTA agencies in 2025 (15%).

Half of the agencies (6/12) presented a decrease in the number of HTA outcomes in 2025 compared to the average from 2021 to 2024, including Canada (CDA-AMC) (26 vs 31), Canada (INESSS) (24 vs 29), France (25 vs 36), Germany (35 vs 36), Ireland (21 vs 22), and Scotland (21 vs 26) (Figure 2).

Figure 2. First HTA Recommendation Across Key Jurisdictions (HTA Recommendations Between 2021-2025)



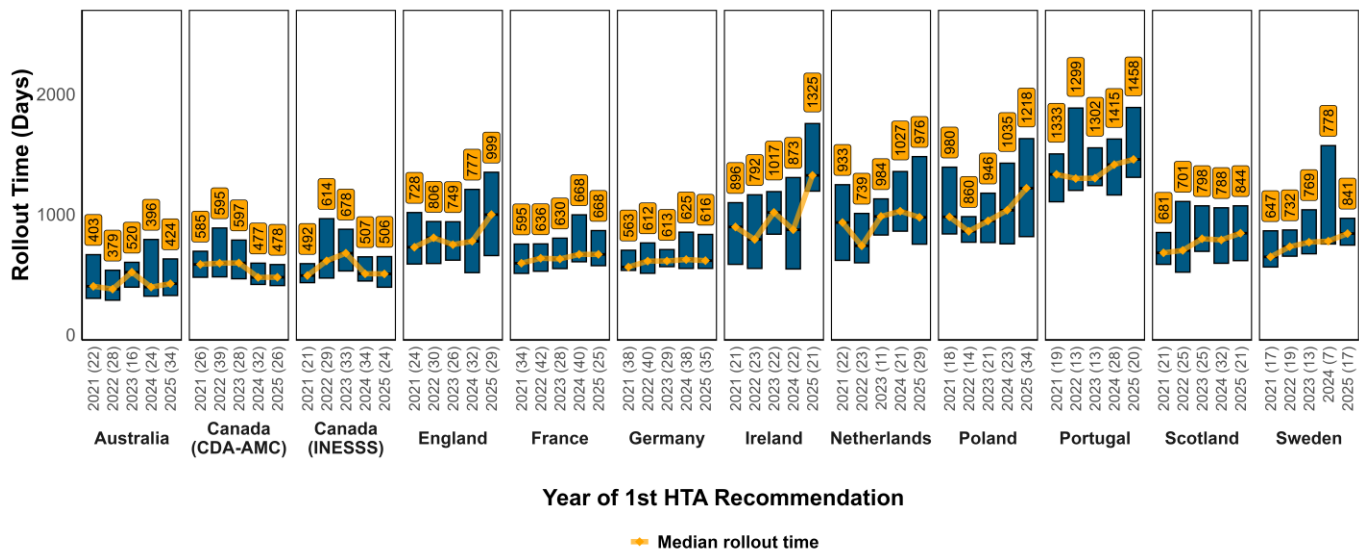
Note: Please note that some countries may include price negotiation as part of their HTA process

n = number of NASs

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Synchronisation of Regulatory and HTA Processes

Figure 3. Regulatory Submission to HTA Recommendation
(HTA Recommendations Between 2021-2025)



n = number of NASS

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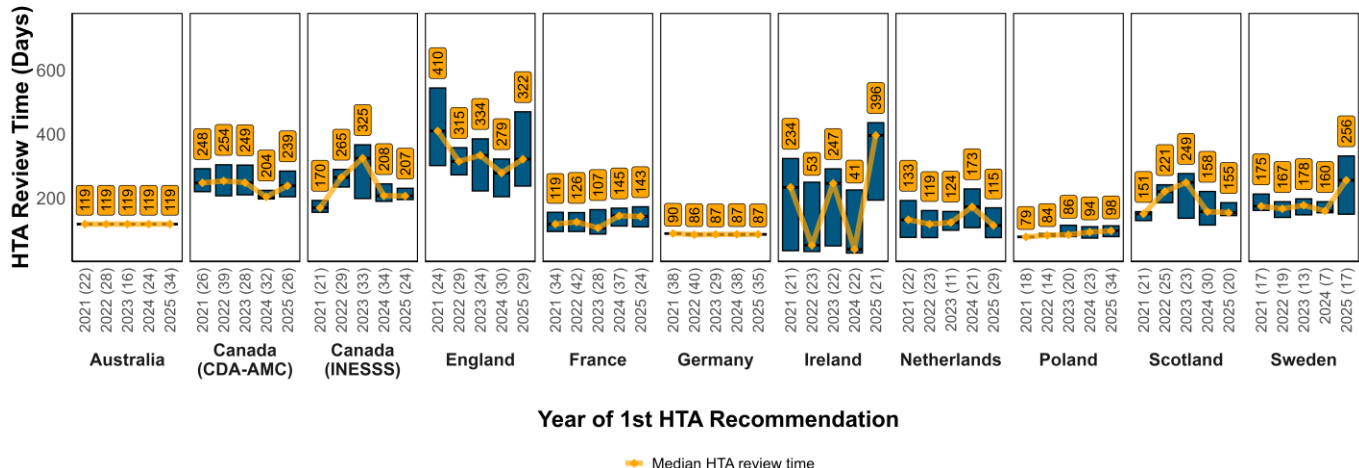
The box represents the interquartile range (from the 1st to the 3rd quartile), and the line inside the box indicates the median

Among the 12 studied agencies, Australia presented the shortest median rollout time from regulatory submission to HTA recommendation in 2025, followed by CDA-AMC (Canada). Germany had the most consistent rollout times from 2021 to 2025.

In 2025, Australia showed the shortest median rollout time from regulatory submission to the first HTA recommendation, completing the process in 424 days (Figure 3). This was followed by Canada (CDA-AMC then INESSS), Germany and France, which required 478, 506, 616, and 668 days, respectively, to reach the first HTA recommendation. Germany showed the highest consistency in the median time to HTA recommendation between 2021-2025, with an overall standard deviation of ± 24 days.

In 2025, Germany demonstrated the fastest HTA review time, completing the process in 87 days. Poland followed closely, with 98 days (Figure 4). The longitudinal data indicated a strong consistency in HTA review times for both Australia and Germany throughout the studied years. In Germany, this predictability is derived from the AMNOG process, which indicates that IQWiG should assess the added therapeutic benefit of a new drug compared to an appropriate comparator within three months of dossier submission. Similarly, Australia's consistency is supported by its formalised HTA procedures, in which PBAC operates under a 17-week timeframe to assess and decide on applications, based on the frequency of its committee meetings.

Figure 4. HTA Review Time by Year of HTA Recommendation
(HTA Recommendations Between 2021-2025)



n = number of NASS

The box represents the interquartile range (from the 1st to the 3rd quartile), and the line inside the box indicates the median

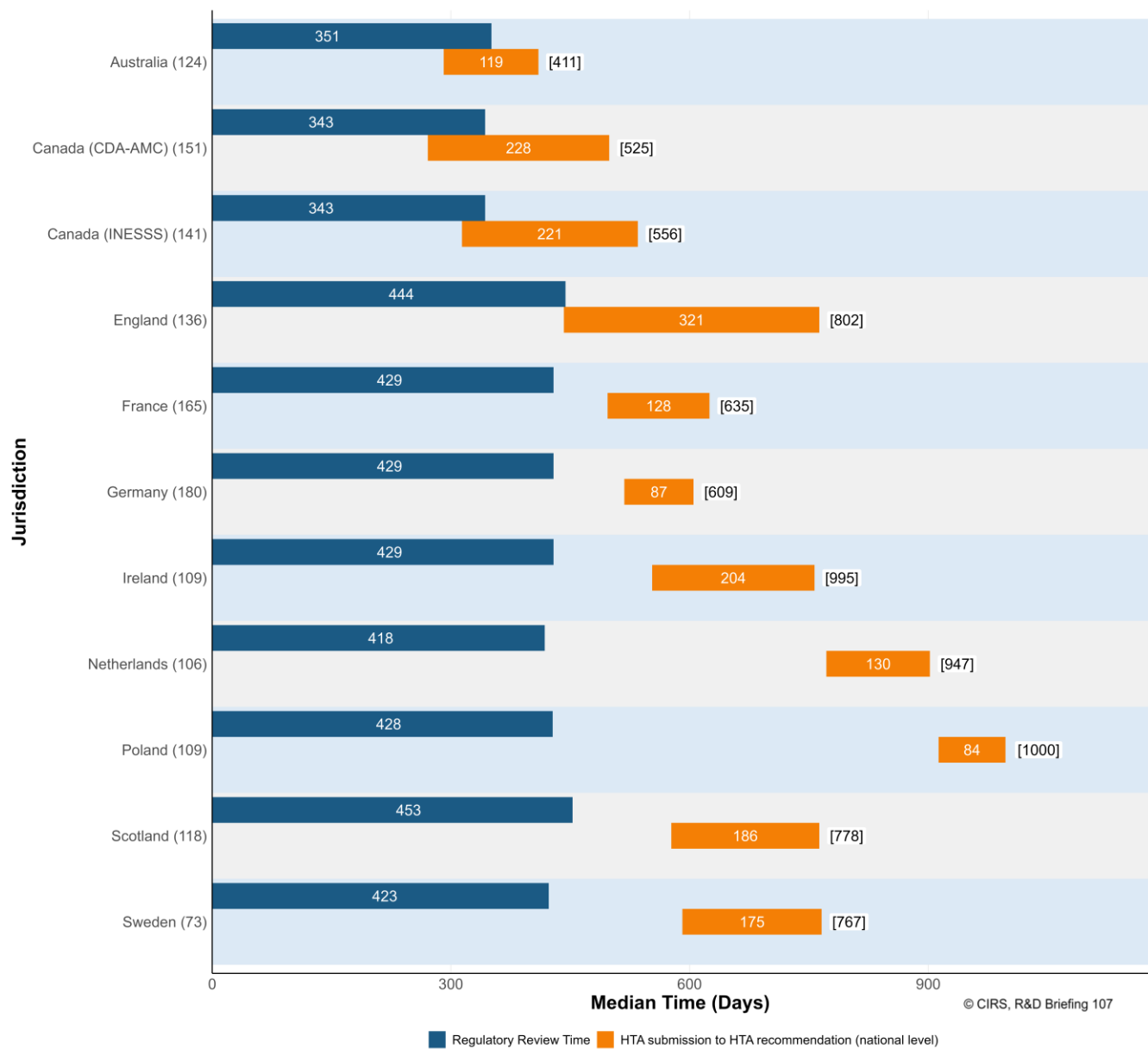
Note 1: Portugal is excluded from this analysis due to the unavailability of their HTA submission dates in the public domain.

Note 2: For Ireland, both rapid and full reviews are included in this analysis. In addition, the HTA review for Ireland time is calculated as (Rapid Review completed - Rapid Review commissioned) + (NCPE assessment completed - Full submission received from applicant).

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Synchronisation of Regulatory and HTA Processes (Cont.)

Figure 5. Breakdown of Rollout Time for NASs by Jurisdiction
(HTA Recommendations Between 2021-2025)



n = number of NASs; Numbers in square brackets represent the overall median rollout time (days).

Note 1: Portugal is excluded from this analysis due to the unavailability of their HTA submission dates in the public domain.

Note 2: For Ireland, both rapid and full reviews are included in this analysis. In addition, the HTA review for Ireland time is calculated as (Rapid Review completed - Rapid Review commissioned) + (NCPE assessment completed - Full submission received from applicant).

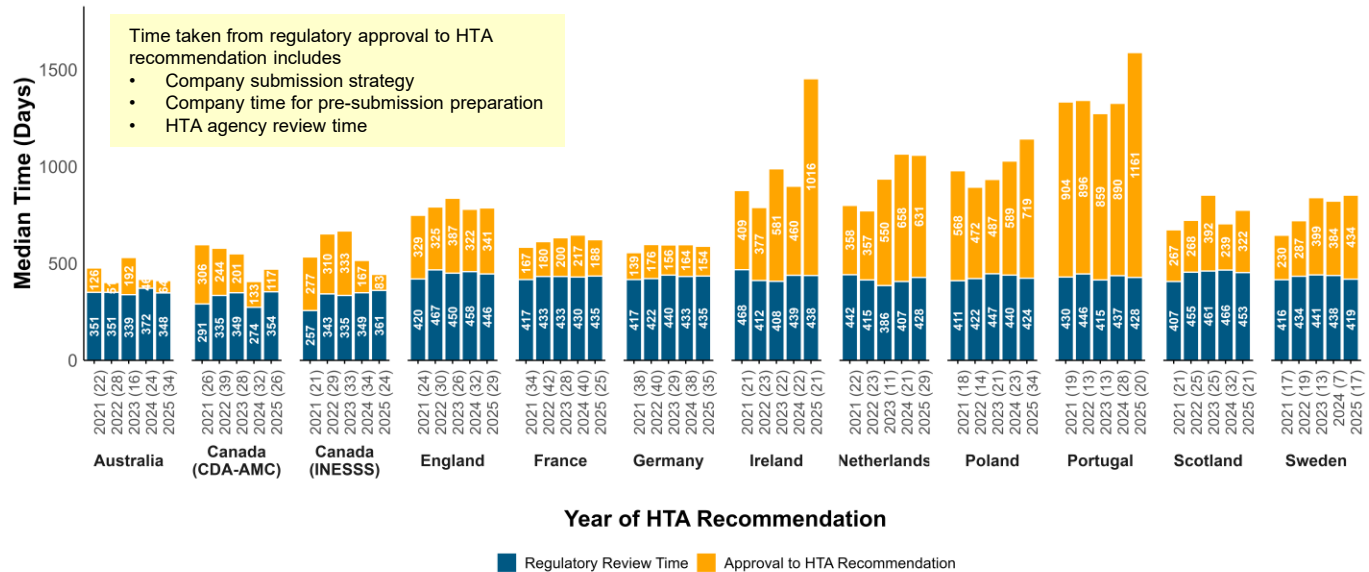
Poland exhibited the fastest median HTA review time for HTA outcomes between 2021 and 2025.

The HTA process varies across different jurisdictions. Australia and Canada (both CDA-AMC and INESSS) allow the HTA process to start before the regulatory approval is granted. England also showed an overlap between its HTA and regulatory processes, as companies are permitted to submit evidence to NICE prior to marketing authorisation. In addition, not all NASs undergo the NICE review process in England. Initially, a scoping phase takes place before marketing authorisation is achieved. Subsequently, companies are invited to submit HTA dossiers to NICE. In Germany, companies can set drug prices freely for the first 6 months after market entry, but they must submit an HTA dossier to G-BA (Federal Joint Committee, Gemeinsamer Bundesausschuss) who then requests IQWiG to assess the added therapeutic benefit of the drug over the appropriate comparator within three months.

Among the studied jurisdictions, Poland presented the shortest median HTA review time for HTA outcomes between 2021 and 2025 (84 days) (Figure 5). However, this expedited process was counterbalanced by a prolonged overall rollout time. This delay is attributed to the longer gap between regulatory approval and HTA submission.

Synchronisation of Regulatory and HTA Processes (Cont.)

Figure 6. Breakdown of Rollout Time Across Key Jurisdictions by Year of HTA Recommendation (HTA Recommendations Between 2021-2025)



n = number of NASS

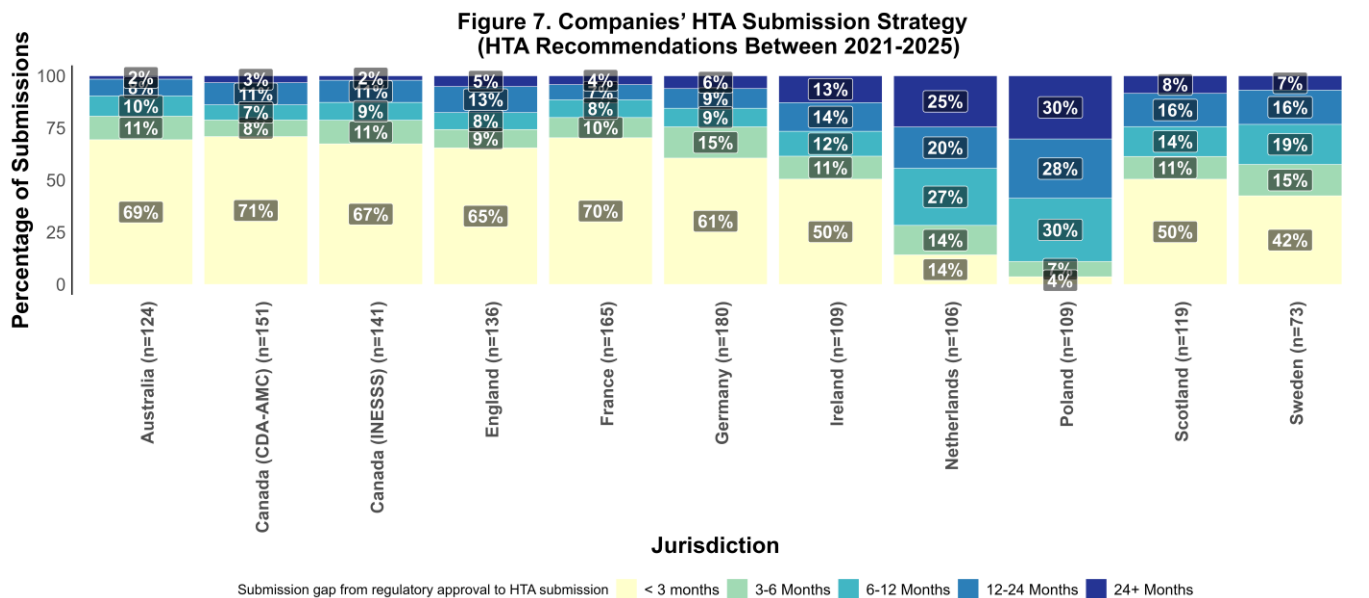
Note: NASS with a missing regulatory review time or missing regulatory approval / HTA recommendation date are excluded from this analysis

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Companies' submission strategies were heterogeneous among the studied jurisdictions.

Figure 6 shows a breakdown of the rollout time across key jurisdictions from 2021 to 2025 with two main components: the regulatory review time and the time from regulatory approval to HTA recommendation. This highlights that some jurisdictions face extensive timelines after regulatory approval. The time from approval to HTA recommendation can be attributed to company submission strategy, company time for pre-submission preparation, and HTA agency review times.

Figure 7 shows the timing of HTA submissions in relation to regulatory approval across 11 jurisdictions. In Australia, Canada (CDA-AMC and INESSS), England, France, and Germany, most HTA submissions occur early - over 60% are submitted no later than three months after regulatory approval. In contrast, the Netherlands and Poland display a different pattern: only 14% or fewer submissions take place no later than three months after approval. Instead, a large proportion of submissions in these countries occur between 3-12 months post-approval, with 25% in the Netherlands and 30% in Poland submitted more than 24 months after approval. These differences underscore the heterogeneity in submission timing across jurisdictions, likely reflecting variation in national HTA requirements, company prioritisation, and resource allocation.



(n) = number of NASS

Note 1: Products for which the HTA submission date is not available in the public domain have been removed from this analysis

Note 2: A submission gap of less than three months may include submissions made prior to regulatory approval

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Characteristics: Regulatory Orphan Designation

Figure 8. Proportion of NAs Assessed by HTA that Held a Regulatory Orphan Designation by Jurisdiction (HTA Recommendations Between 2021-2025)

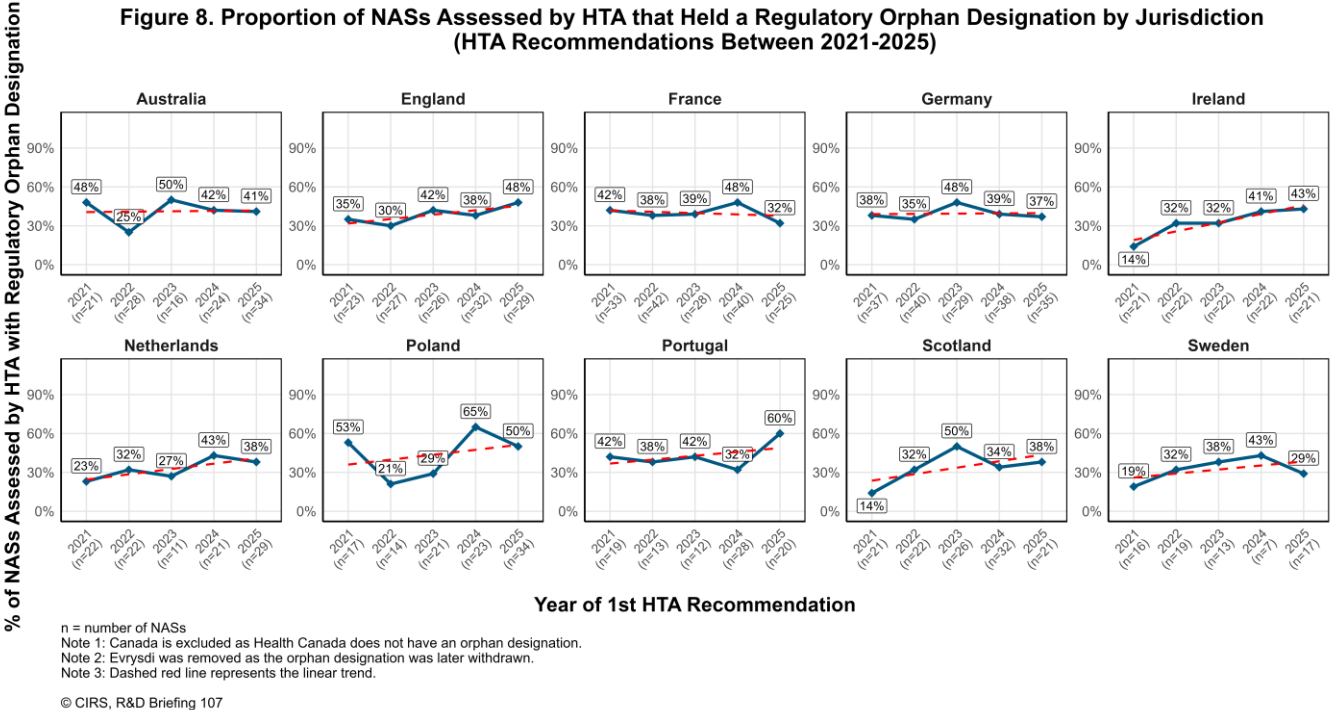
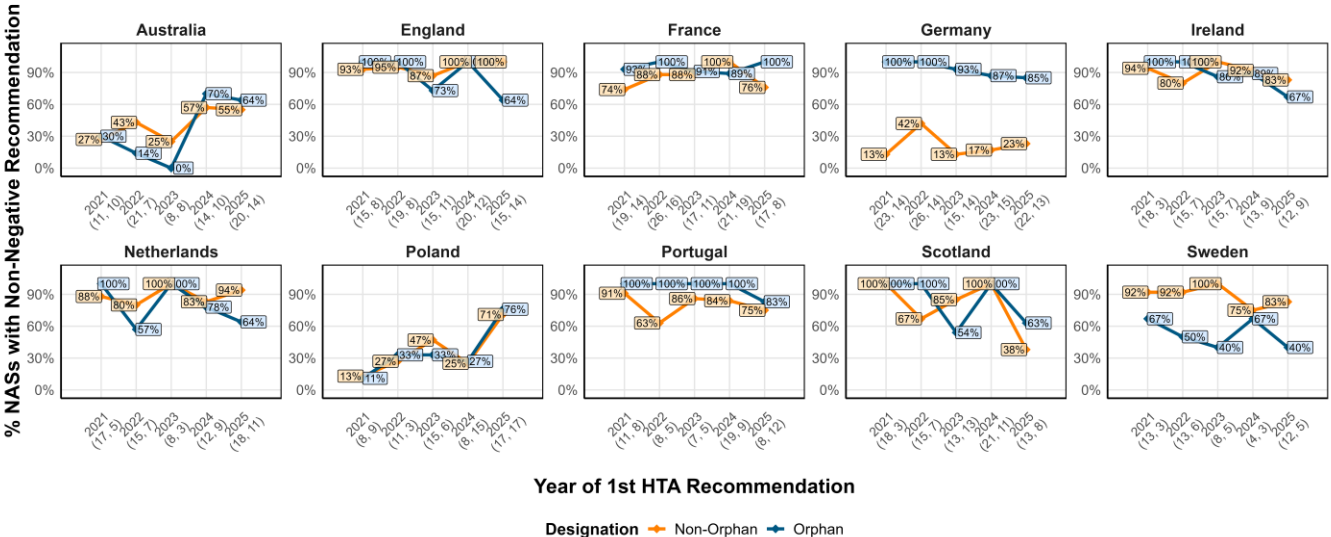


Figure 8 shows the proportion of HTA recommendations for NAs with a regulatory orphan designation, by year of first HTA recommendation and jurisdiction. Overall, the proportion of HTA recommendations involving orphan-designated NAs fluctuated over the past five years across all jurisdictions. In 2025, Portugal had the highest proportion (60%), followed by Poland (50%) and England (48%). Sweden had the lowest proportion in 2025 (29%).

Figure 9 displays the proportion of NAs receiving a non-negative HTA recommendation, stratified by regulatory orphan designation status, year of recommendation, and jurisdiction. Notable cross-country variation was observed, with Germany showing a clear advantage for orphan medicines due to the fact added benefit is proven, Poland demonstrating improving outcomes over time, and several jurisdictions exhibiting declining non-negative recommendation rates by 2025.

Figure 9. Proportion of NAs With a Non-Negative HTA Recommendation: Orphan vs Non-Orphan by Jurisdiction (HTA Recommendations Between 2021-2025)

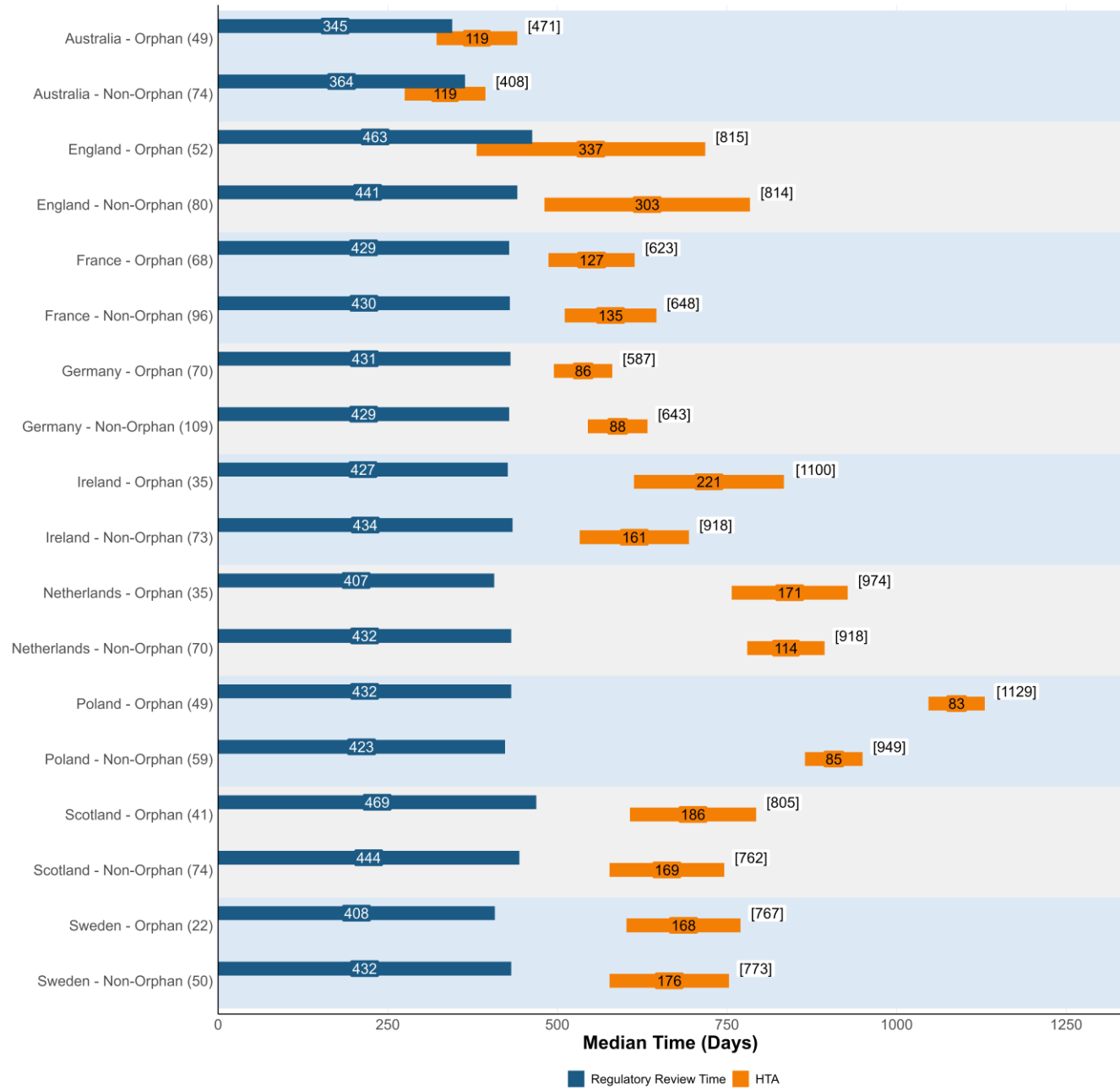


Note 1: Canada is excluded as Health Canada does not have an orphan designation.
Note 2: Evrysdi was removed as the orphan designation was later withdrawn.
Note 3: Non-negative outcomes include 'Positive', 'Positive with restrictions', and 'Multiple'.
Note 4: Numbers in parentheses under each year denote the number of non-orphan and orphan NAs, respectively (non-orphan, orphan).

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Characteristics: Regulatory Orphan Designation (Cont.)

Figure 10. Breakdown of Rollout Time for NAs by Orphan Designation (HTA Recommendations Between 2021-2025)



n = number of NAs; Numbers in square brackets represent the overall median rollout time (days). Note 1: Canada is excluded from this analysis because Health Canada does not have an orphan designation. Portugal is also excluded from this analysis due to the unavailability of their HTA submission dates in the public domain. Note 2: Evrysdi was removed from this analysis as EMA evaluated this product as an orphan drug, but the orphan designation was later withdrawn. Note 3: For Ireland, both rapid and full reviews are included in this analysis. In addition, the HTA review for Ireland time is calculated as (Rapid Review completed - Rapid Review commissioned) + (NCPE assessment completed - Full submission received from applicant). © CIRS, R&D Briefing 107

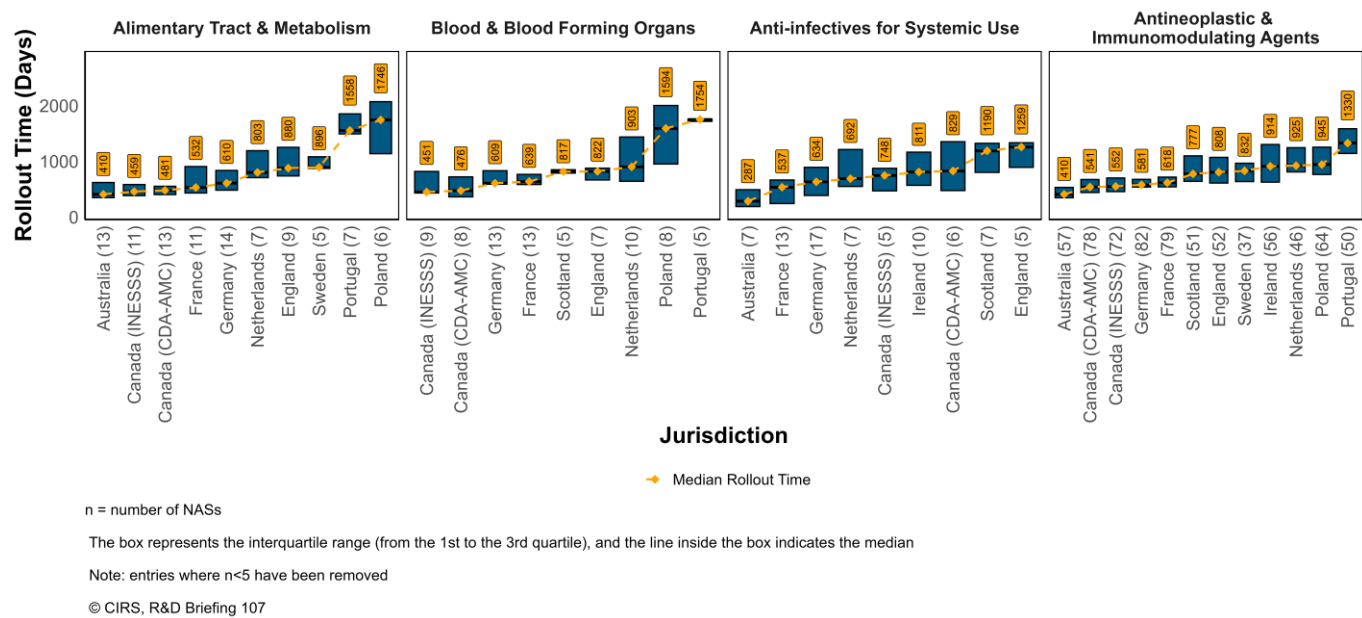
Longer submission gaps for orphan products may lead to longer overall rollout times.

The orphan designation is employed by regulatory agencies such as the Australian Therapeutic Goods Administration (TGA), European Medicines Agency (EMA), and UK Medicines and Healthcare products Regulatory Agency (MHRA) to incentivise companies to research and develop medicines for rare diseases that otherwise would not be developed. In our analysis of England and Scotland, if a product was approved via a reliance mechanism on the EMA decision (e.g. through the European Commission Decision Reliance Procedure (ECDRP) or the International Recognition Procedure (IRP)), the EMA orphan designation was applied. Alternatively, if the product was approved through a national route by the MHRA, the MHRA orphan designation was used. It is worth noting that Health Canada does not have an orphan drug policy.

Differences between orphan and non-orphan NAs in regulatory review time were within 25 days in every jurisdiction and did not follow a consistent direction (Figure 10). Differences in overall rollout time were larger: median rollout was longer for orphan NAs in Poland, Ireland, the Netherlands, Scotland and Australia. These differences may reflect longer submission gaps for orphan products, notably in Poland, Ireland and Australia, as well as longer HTA review times for orphan NAs in Ireland and the Netherlands.

Characteristics: Therapeutic Area

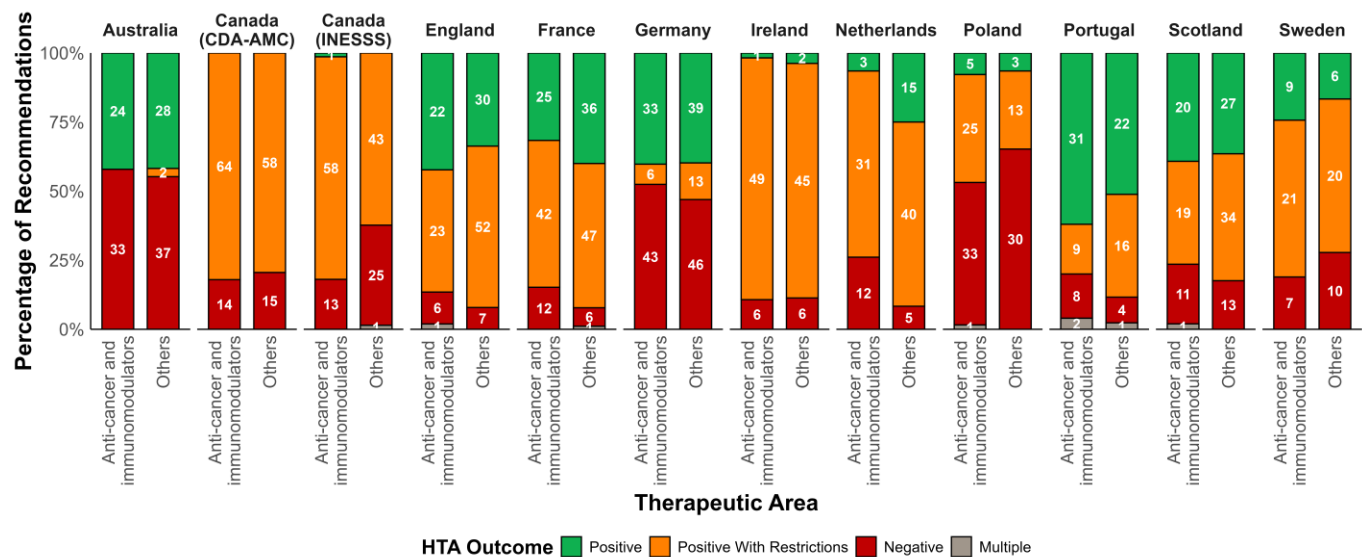
Figure 11. Regulatory Submission to 1st HTA Recommendation by Therapeutic Area (HTA Recommendations Between 2021-2025)



The top four therapeutic areas made up 66% (199/300) of the unique products assessed by HTA in at least one country between 2021-2025, with anti-cancer and immunomodulators making up 64% (127/199) of the top therapeutic areas (Figure 11). Australia was the fastest for Alimentary Tract and Metabolism, Anti-infectives for Systemic Use, and Antineoplastic and Immunomodulators in terms of median rollout time from regulatory submission to HTA outcome (Figure 11). As noted by the 25th-75th percentile bars, there were also wide variations for certain jurisdictions across therapy areas. The variation in rollout time may be attributed to expedited review pathways by regulatory agencies, companies' submission strategy (parallel vs. sequential), and time taken during the HTA process.

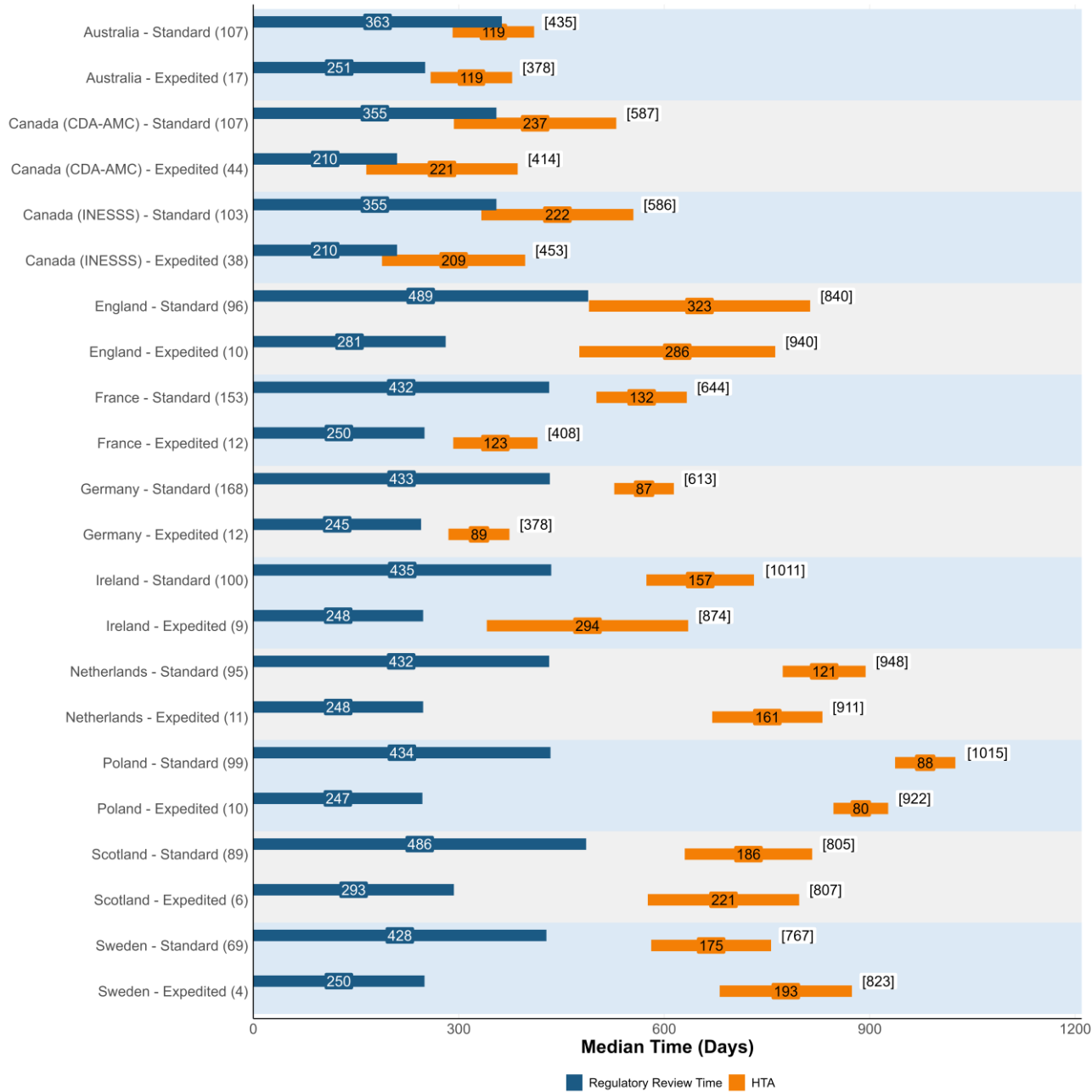
England and Ireland recorded the highest proportions of non-negative recommendations (positive and positive with restrictions) for anti-cancer and immunomodulator NASS, at 87% and 89%, respectively (Figure 12).

Figure 12. 1st HTA Recommendation: Anti-Cancer and Immunomodulators vs. Other (HTA Recommendations Between 2021-2025)



Characteristics: Expedited and Flexible Pathways

Figure 13. Breakdown of Rollout Time for NASs by Regulatory Review Type (HTA Recommendations Between 2021-2025)



n = number of NASs; Numbers in square brackets represent the overall median rollout time (days). Note 1: Portugal is excluded from this analysis due to the unavailability of their HTA submission dates in the public domain. Note 2: For Ireland, both rapid and full reviews are included in this analysis. In addition, the HTA review for Ireland time is calculated as (Rapid Review completed - Rapid Review commissioned) + (NCPE assessment completed - Full submission received from applicant). © CIRS, R&D Briefing 107

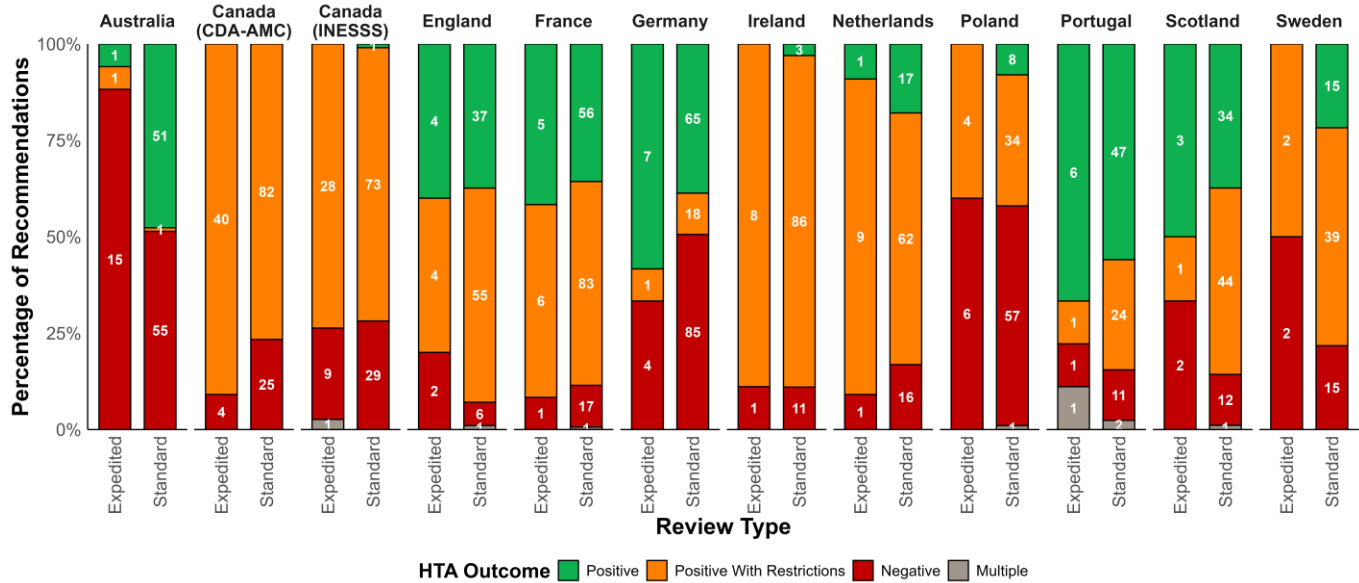
Products reviewed through expedited regulatory pathways presented shorter overall rollout times in all countries, except for England, Scotland, and Sweden.

Expedited regulatory pathways are mechanisms designed to accelerate the review process of innovative products that are intended to address unmet medical needs or significant concerns related to public health. The list of expedited regulatory pathways across all jurisdictions is elaborated in the Appendix ([Facilitated regulatory pathways](#)). ‘Expedited review’ refers to EMA ‘Accelerated Assessment’ and Health Canada/TGA ‘Priority Review’.

In all jurisdictions except in England, Scotland, and Sweden (**Figure 13**), the median time from regulatory submission to HTA recommendation was shorter for products undergoing expedited review compared to those following the standard process. The data suggest this trend is driven by the shorter regulatory review times of expedited pathways, which may have generally enabled an earlier start of the HTA review process. However, shorter regulatory review times did not always translate to shorter overall rollout times. In Sweden, although expedited products presented quicker regulatory reviews, delayed submissions for HTA assessment may have contributed to longer overall rollout times.

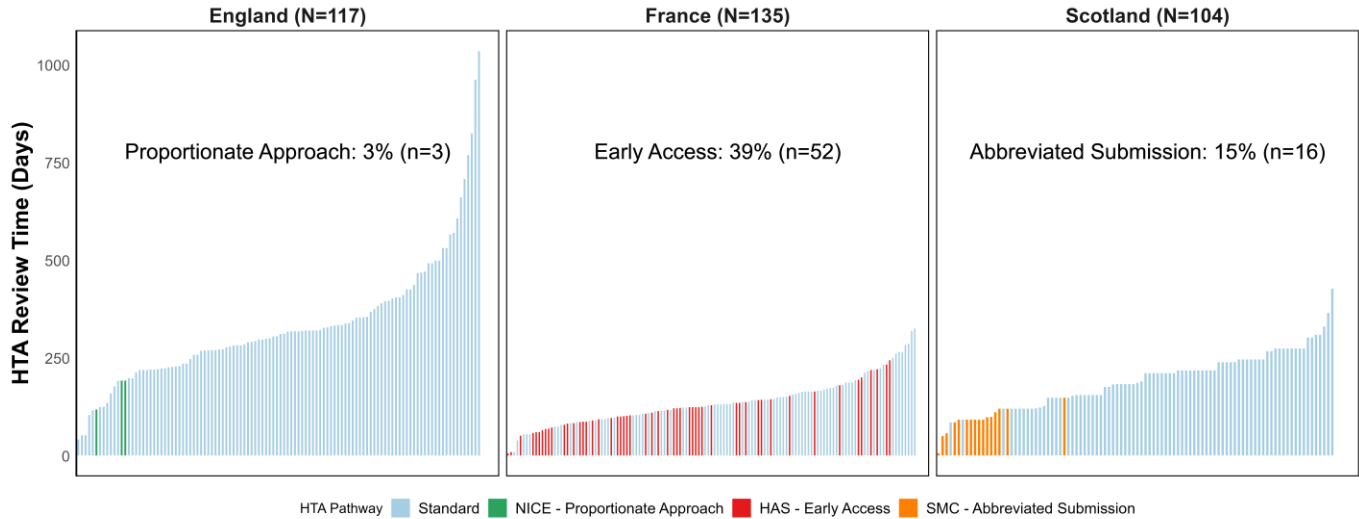
Characteristics: Expedited and Flexible Pathways (Cont.)

Figure 14. First HTA Recommendation Outcomes by Regulatory Review Type (HTA Recommendations Between 2021-2025)



Across jurisdictions, the proportion of positive or positive-with-restrictions outcomes varied between expedited and standard reviews (Figure 14). In Canada (both CDA-AMC and INESSS), France, Germany, and the Netherlands, expedited reviews showed a higher proportion of favourable outcomes than standard reviews. Australia had the highest proportion of expedited reviews receiving a negative first recommendation: 88% (15/17), compared with 51% (55/107) via the standard route. Several jurisdictions have introduced flexible, adaptive processes: England's Proportionate Approach (2022), France's Early Access Pathway (2021), and Scotland's abbreviated submissions (2020). The proportion of NAs going through these special pathways varied (Figure 15): 39% (n=52) in France via Early Access, 15% (n=16) in Scotland via abbreviated submission, and 3% (n=3) in England via the Proportionate Approach. In each jurisdiction, median HTA review times were shorter for products using the special pathway than for those following the standard route: 115 days [IQR 88-139] versus 145 days [111-177] in France, 95 days [93-105] versus 214 days [158-249] in Scotland, and 195 days versus 315 days [238-393] in England, although the England comparison rests on only three products.

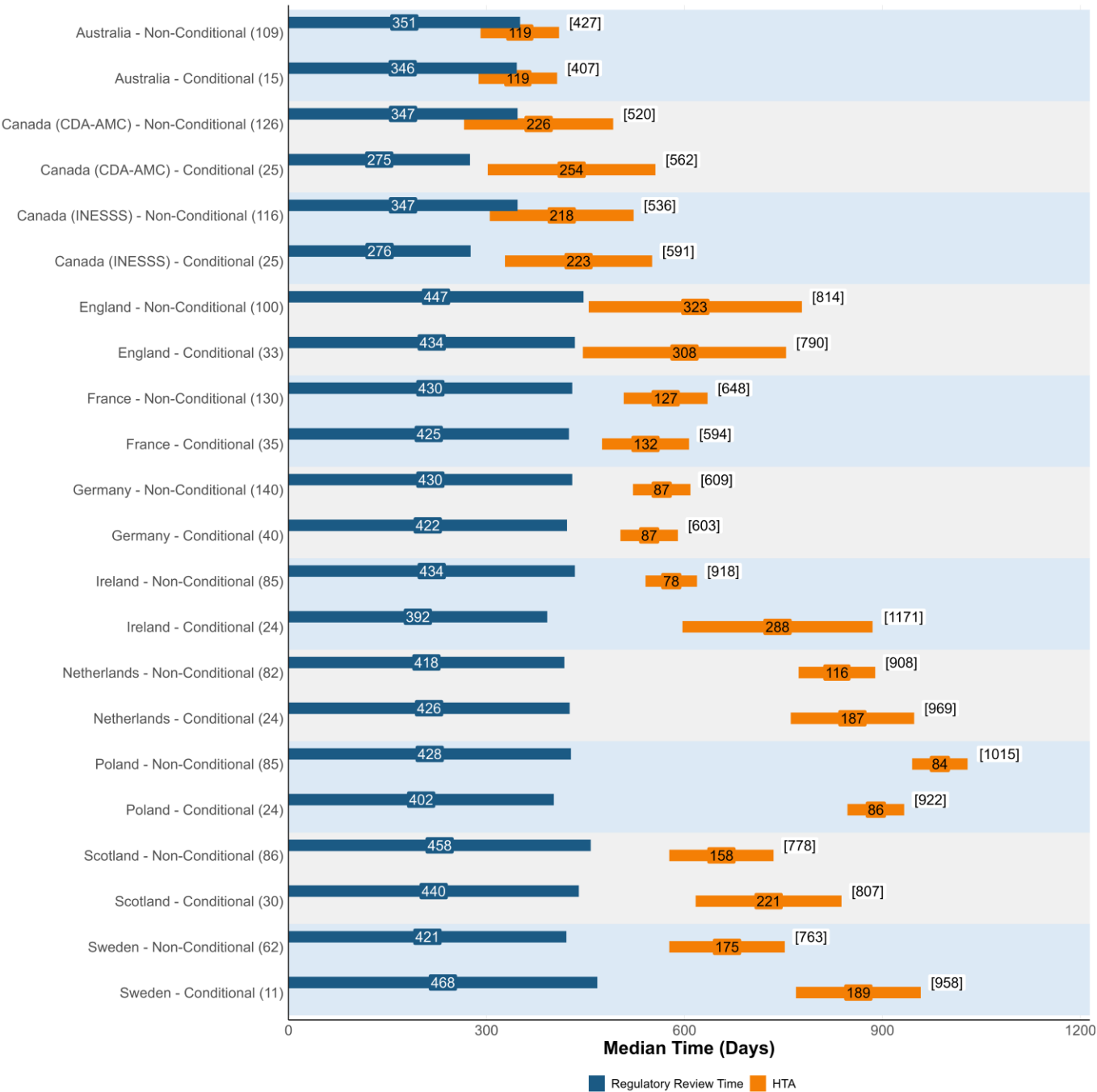
Figure 15. Proportion of Special Pathways in England, France, and Scotland (HTA Recommendations 2022-2025)



(n) = number of NAs
Note: Each bar represents a NAS
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Characteristics: Conditional Regulatory Approval

Figure 16. Breakdown of Rollout Time for NAs by Conditional Status (HTA Recommendations Between 2021-2025)



n = number of NAs; Numbers in square brackets represent the overall median rollout time (days). Note 1: Portugal is excluded from this analysis due to the unavailability of their HTA submission dates in the public domain. Note 2: For Ireland, both rapid and full reviews are included in this analysis. In addition, the HTA review for Ireland time is calculated as (Rapid Review completed - Rapid Review commissioned) + (NCPE assessment completed - Full submission received from applicant). © CIRS, R&D Briefing 107

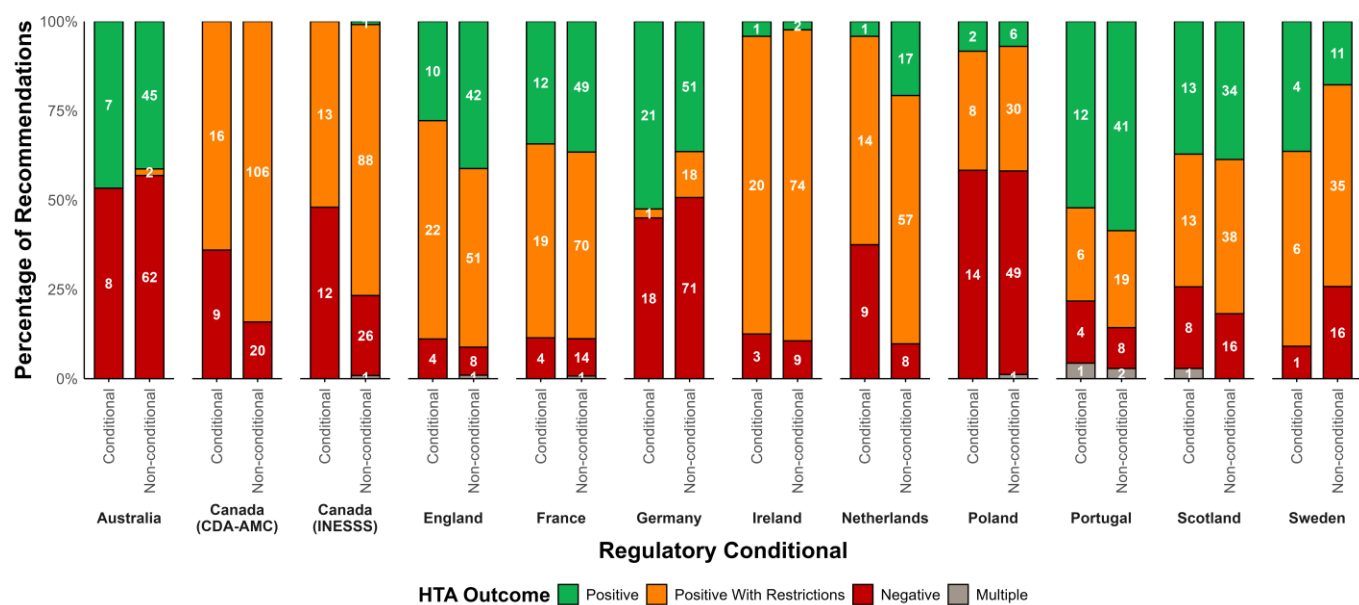
In approximately half of the studied jurisdictions (6/11), the conditional pathway presented a longer median rollout time.

Regulatory agencies in Australia, Canada, Europe and the UK have implemented conditional pathways to facilitate the marketing of promising new medicines in situations where clinical evidence is limited. The list of conditional regulatory pathways across the studied jurisdictions is elaborated in the Appendix ([Facilitated regulatory pathways](#)).

In 6 out of 11 studied jurisdictions, NAs approved through a conditional regulatory pathway exhibited longer median rollout times to HTA recommendation compared to those that followed non-conditional pathways (Figure 16). This trend was observed in Canada (both CDA-AMC and INESSS), Ireland, the Netherlands, Scotland, and Sweden.

Characteristics: Conditional Regulatory Approval (Cont.)

Figure 17. First HTA Recommendation by Regulatory Conditional Status
(HTA Recommendations Between 2021-2025)



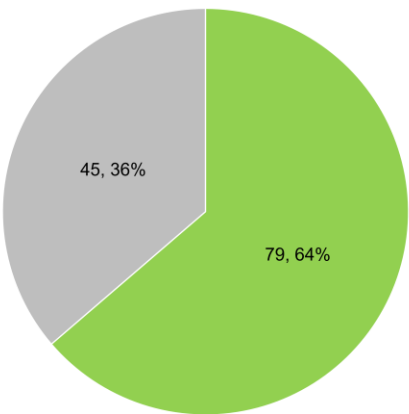
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Figure 17 compares the distribution of first HTA outcomes for NASs across 12 jurisdictions, segmented by regulatory conditional status (conditional vs. non-conditional approvals). The findings in Figure 17 did not indicate a trend between a regulatory conditional approval and obtaining an optimal or non-optimal HTA recommendation, suggesting that HTA systems differ in how they manage regulatory uncertainty.

Alongside Figure 16, these analyses suggest that uncertainty from a regulatory conditional approval can be absorbed by HTA systems through longer review time and conditions rather than through rejection. In the six jurisdictions where conditional products showed longer median rollout times, the direction of any difference in HTA outcome distribution was not consistent. In Ireland, the distributions of non-negative outcomes for conditional vs. non-conditional approvals were closely comparable (88% vs 89%), and in Sweden conditional products were more likely to receive a non-negative recommendation (91% vs 74%). In Canada and the Netherlands, however, the proportion was 20 to 27 percentage points lower for conditional products (64% vs 84% for CDA-AMC, 52% vs 77% for INESSS, and 63% vs 90% for ZIN). There was a smaller difference in Scotland (74% vs 82%). These comparisons should be interpreted with caution given the small number of conditional approvals assessed in each jurisdiction. Taken together, the data suggest that HTA systems respond to the additional evidentiary uncertainty of a conditional approval in different ways: in most jurisdictions through a longer assessment and, where positive, a recommendation carrying restrictions, but in Canada and the Netherlands also through a higher proportion of negative first recommendations.

Features of Australia

Figure 18. Proportion of NASs Assessed by PBAC That Received Reimbursement in Australia (Reviewed by PBAC Between 2021-2025)



Reimbursement Status ■ Non-reimbursed (Not listed on PBS) ■ Reimbursed (PBS listed)
number of NASs / Percentage

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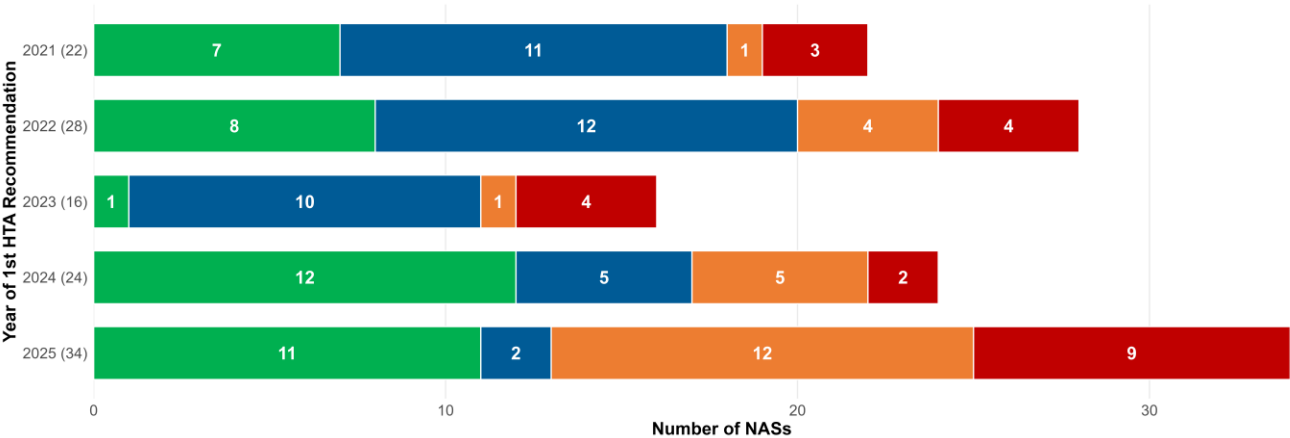
Of the 124 NASs reviewed by the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia between 2021-2025, 64% have been listed on the Pharmaceutical Benefits Scheme (PBS).

In Australia, under the PBS, the government subsidises the cost of medicine for most medical conditions. PBAC is an independent expert body appointed by the Australian Government, consisting of doctors and health professionals, among others. Its primary role is to recommend new medicines for listing on the PBS. No new medicine can be listed without a positive or positive with restrictions recommendation from the committee. 64% of the NASs that were assessed by PBAC between 2021 and 2025 have been PBS-listed (Figure 18). The remaining 36% are NASs that either have been recommended for reimbursement by PBAC but have not been PBS-listed yet, or NASs that have not been recommended for reimbursement by PBAC (i.e. they have received a negative HTA recommendation).

Figure 19 shows a breakdown of the PBS listing status of NASs reviewed by PBAC between 2021 and 2025, by year of HTA recommendation.

Figure 19. The PBS Listing Status for NASs Reviewed by PBAC (HTA Recommendations Between 2021-2025)

■ Recommended by PBAC at first submission and listed
■ Recommended by PBAC at resubmission and listed
■ Recommended by PBAC at first submission or at resubmission but not listed yet
■ Not recommended by PBAC either at first submission or resubmission*, therefore not listed



* Including products not resubmitted by companies

(n) = number of NASs

Note: These data are subject to right censoring. Products recommended more recently have had less time to reach listing, so the same products may show different timelines and outcomes in future analyses.

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Features of Australia (Cont.)

Figure 20. Breakdown of Time to Listing by PBAC 1st Recommendation Year
(Reviewed by PBAC Between 2021-2025)

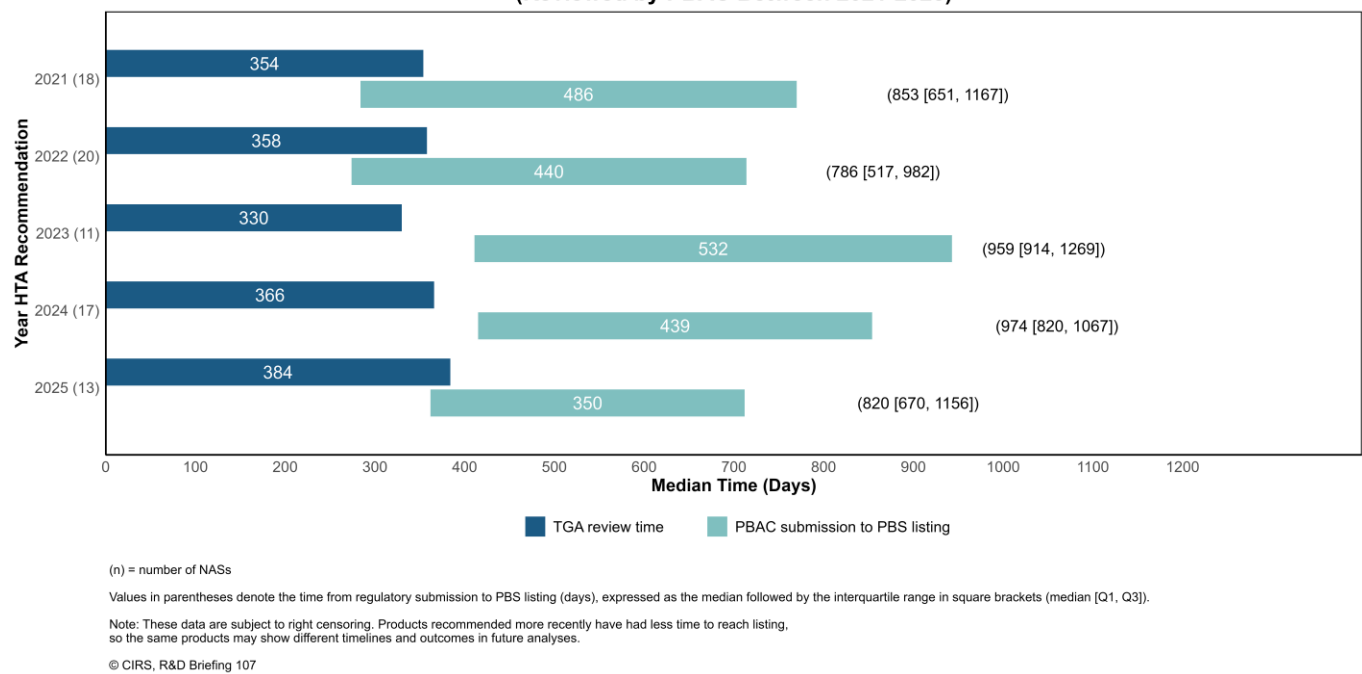
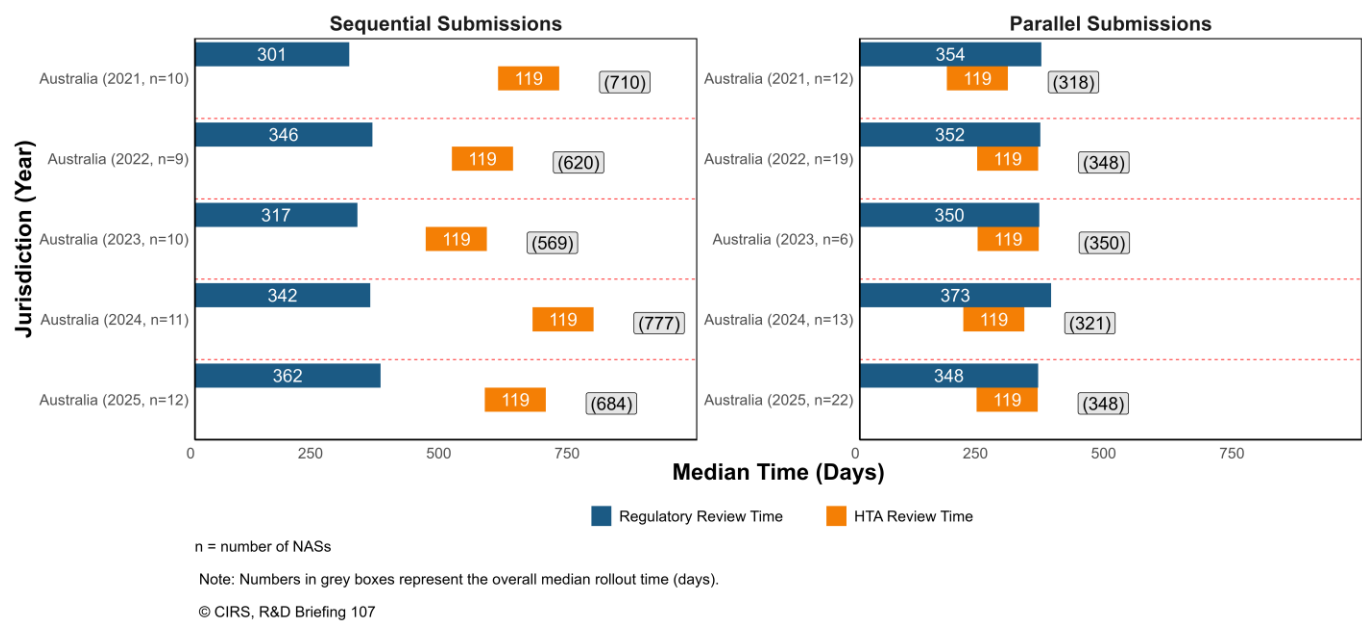


Figure 20 displays the breakdown of time to PBS listing in Australia. TGA review time stayed relatively stable across the five years (ranging from 330 to 384 days). The data suggest that most of the variation in total rollout came from the PBAC-submission-to-listing phase, which fluctuated more widely (350 to 532 days). The PBAC-submission-to-listing segment is measured from the first PBAC submission to 1st PBS listing, which is only possible after a 1st positive/positive with restriction PBAC recommendation. This segment therefore absorbs any resubmission cycles a product went through before that positive/positive with restrictions recommendation. Since no medicine can be PBS-listed without a positive or positive-with-restrictions recommendation, products requiring a second or third resubmission cycle due to negative HTA recommendations accumulate additional months in this phase while TGA review time remains unchanged.

Features of Australia (Cont.)

Figure 21. Breakdown of Rollout Time by Review Sequence in Australia (Reviewed by PBAC Between 2021-2025)



Parallel submissions in Australia consistently present faster median rollout times compared to sequential submissions.

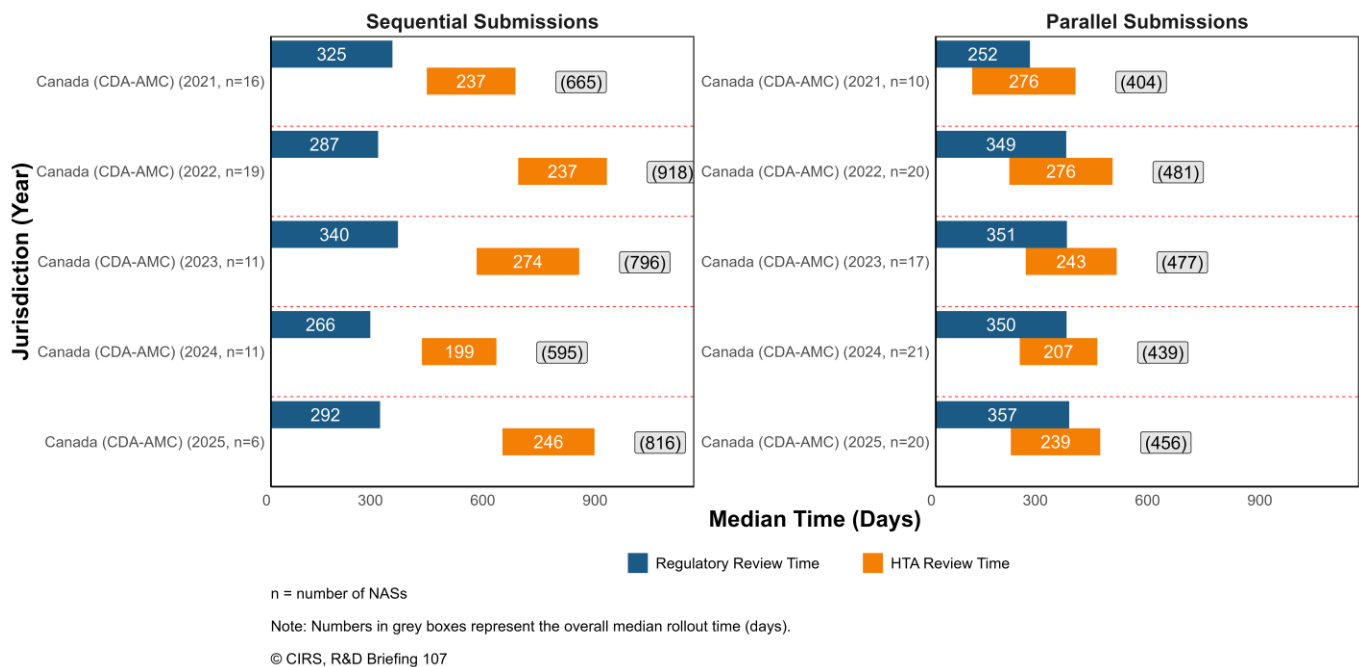
In Australia, companies can submit the HTA dossier to PBAC either before TGA approval, known as the parallel process, or after TGA approval, known as the sequential process. Under the TGA/PBAC parallel process, the TGA Delegate's Overview informs the PBAC's review of a drug, and companies may submit the Delegate's Overview up to one week before the PBAC meeting.

The Australian parallel process consistently presented a shorter overall median time from regulatory submission to HTA recommendation compared to sequential submissions every year from 2021 to 2025 (Figure 21). Notably, neither the regulatory nor HTA review phase is faster under the parallel process (i.e., PBAC review time was 119 days every year for both routes, and TGA review time varied only narrowly). The difference in total rollout therefore is suggested to come almost entirely from the submission gap, which parallel submissions eliminate by submitting the PBAC dossier before TGA approval.

The uptake of the parallel process in Australia varied over time. Parallel submissions accounted for 55% of NASs in 2021, rising to 68% in 2022, before falling to 38% in 2023. These then recovered to 54% in 2024 and returned to 65% in 2025.

Features of Canada

Figure 22. Breakdown of Rollout Time by Review Sequence in Canada (CDA-AMC)
(Reviewed by CDA-AMC Between 2021-2025)

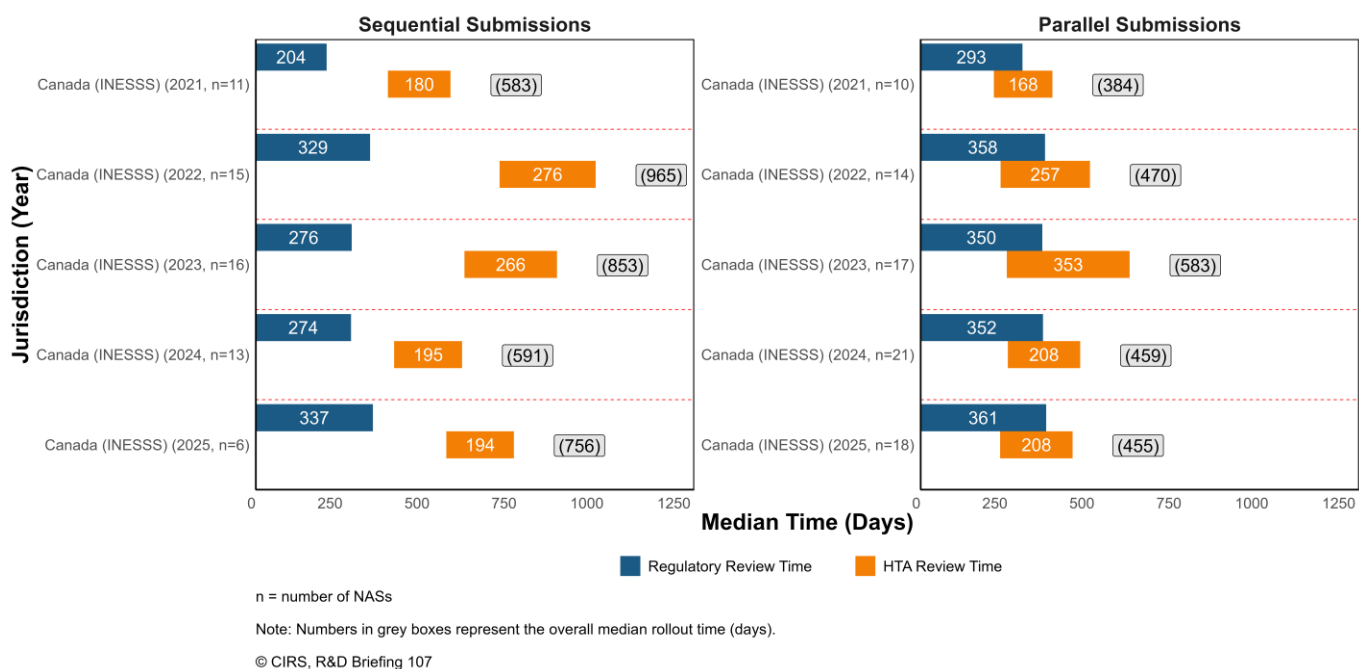


Products submitted to either CDA-AMC or INESSS through the parallel regulatory/HTA process had a faster median rollout time than those submitted sequentially.

A parallel regulatory/HTA review pathway is available for submissions to CDA-AMC and INESSS. This process allows companies to submit to either HTA agency up to 180 days prior to the anticipated Notice of Compliance (NOC) from Health Canada. For both CDA-AMC and INESSS, NASs submitted via the parallel process consistently showed a shorter median rollout time from regulatory submission to HTA recommendation each year (see Figures 22 and 23, respectively).

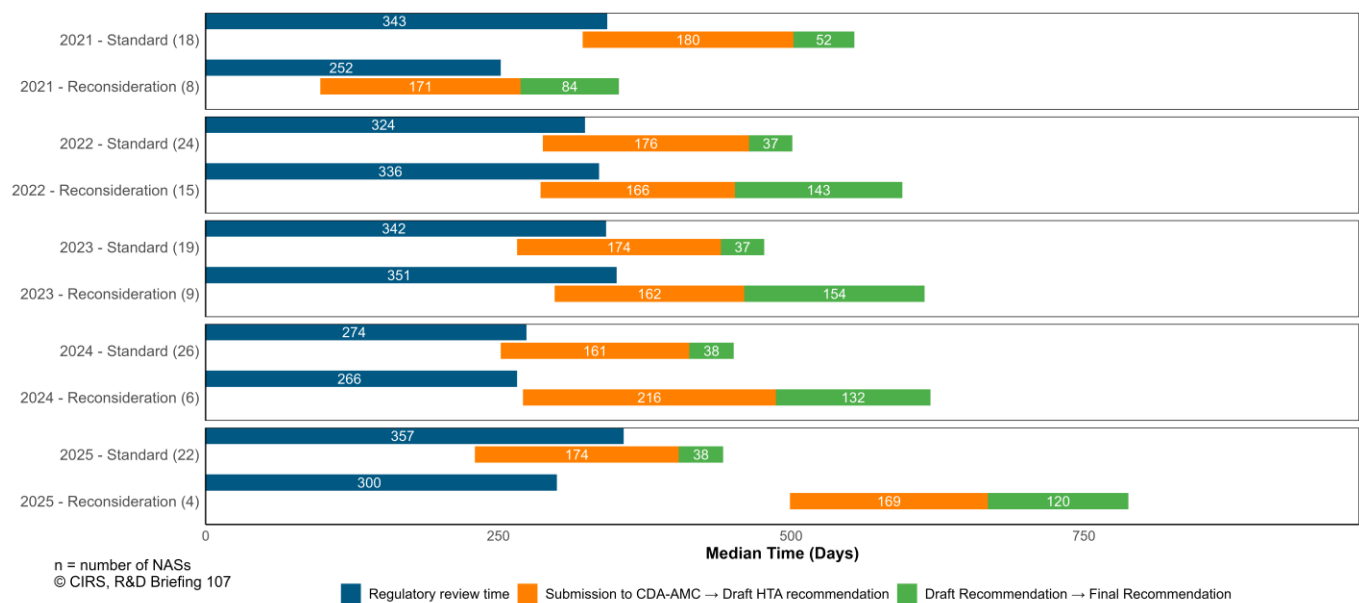
Uptake of the parallel pathway generally increased over time for both agencies. At CDA-AMC, parallel submissions rose every year, from 38% of NASs in 2021 to 51% in 2022, 61% in 2023, 66% in 2024 and 77% in 2025. INESSS followed a similar upward trend, from 48% in 2021 to 75% in 2025.

Figure 23. Breakdown of Rollout Time by Review Sequence in Canada (INESSS)
(Reviewed by INESSS Between 2021-2025)



Features of Canada (Cont.)

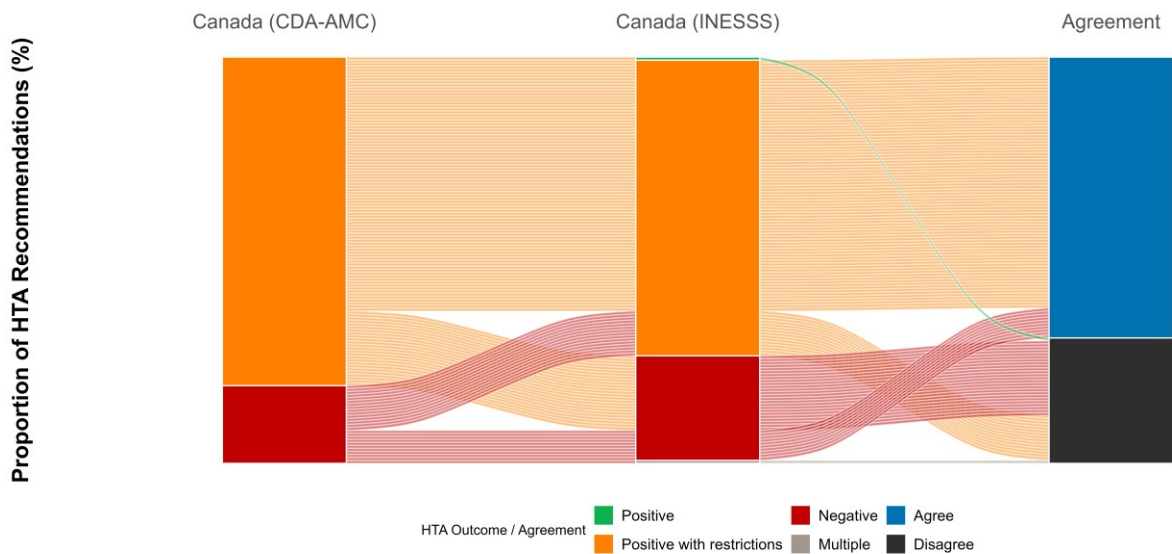
Figure 24. Breakdown of rollout time in CDA-AMC between 2021-2025 (Requested Reconsideration vs Standard)



The applicant for a drug with a draft recommendation may file a request to CDA-AMC for reconsideration of the recommendation during the feedback period. Such a request can be made only on the grounds that the recommendation is not supported by the evidence that had been submitted or by the evidence identified in the review report. **Figure 24** shows that requests for reconsideration extended the median time from the initial draft recommendation to the final recommendation by CDA-AMC compared to no request. In addition, the proportion of NASs for which a reconsideration was requested has declined over time. Requests peaked at 38% of CDA-AMC recommendations in 2022 (15/39) and have decreased since, to 32% in 2023, 19% in 2024 and 15% in 2025. This may suggest improved alignment between sponsors and CDA-AMC at first submission.

A total of 136 NASs received HTA outcomes from both CDA-AMC and INESSS between 2021 and 2025 (**Figure 25**). Of these, 90% (122/136) were first submitted to CDA-AMC, 7% (10/136) were submitted to INESSS first, and 3% (4/136) were submitted to both agencies at the same time. 63% were first recommended by CDA-AMC. Both jurisdictions agreed on the type of HTA recommendation for 69% (94/136) of the common compounds and published different outcomes for the remaining 31%. Such discrepancies may be attributed to differences in their evaluation frameworks. HTA outcomes influence the next step in the reimbursement process: price negotiations. Divergent HTA outcomes can potentially result in variations in access to new medicines across Canadian provinces.

Figure 25. First HTA recommendation comparison of common NASs (n=136) reviewed in Canada (HTA Recommendations Between 2021-2025)



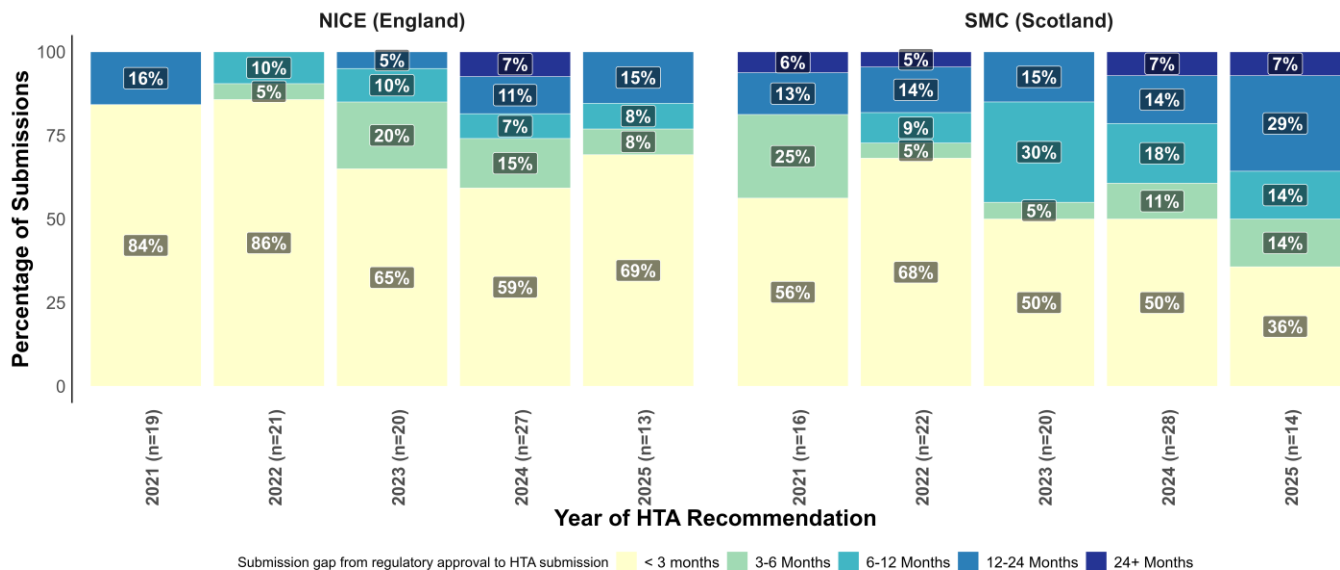
Agreement between CDA-AMC and INESSS: 69%; Disagreement: 31%

Note: each flow represents one HTA recommendation for one NAS

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Features of the UK

Figure 26. Companies' HTA Submission Strategy for Common Compounds (n=100)
(NICE vs SMC, HTA Recommendations 2021-2025)

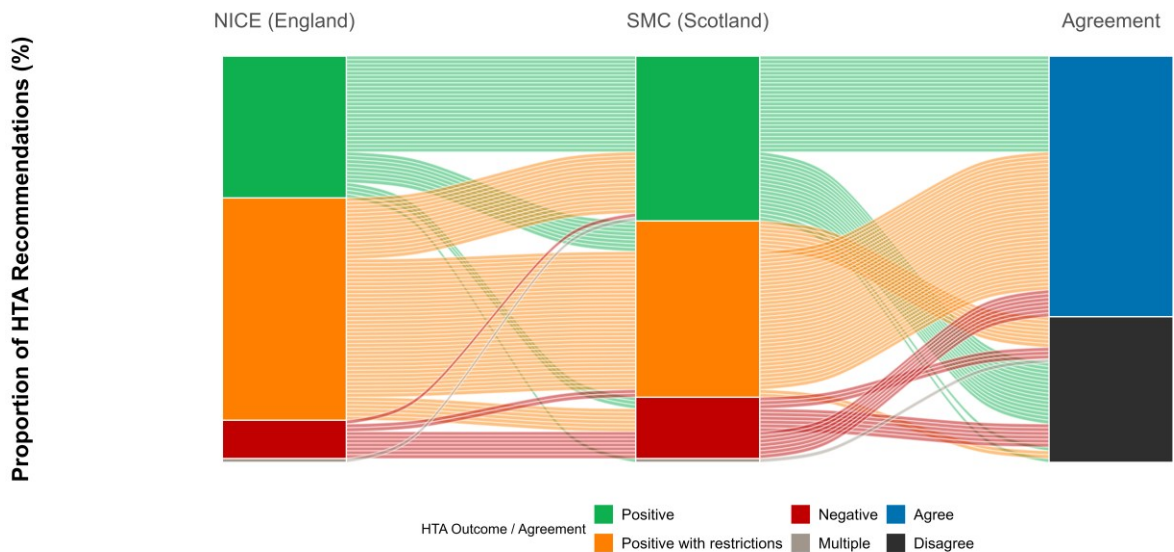


n = number of NASS. Only compounds assessed by both NICE and SMC are included.
Note 1: Products with a missing HTA submission date or regulatory approval date were excluded from both jurisdictions, so that the same compounds are compared.
Note 2: Percentages may not sum to 100% due to rounding.
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Figure 26 shows companies' HTA submission strategy for compounds reviewed by both NICE (England) and SMC (Scotland) between 2021 and 2025, measured as the gap between regulatory approval and HTA submission. Of the common compounds, 89% (89/100) were submitted first to NICE and 59% (59/100) were recommended first by NICE. Most compounds were submitted to NICE within three months of approval throughout (59-86%). For SMC, the proportion submitted within three months fell from 56% in 2021 to 36% in 2025, while those submitted 12-24 months after approval rose to 29%.

Figure 27 compares the first HTA recommendation from NICE and SMC for common NASS in the UK. Both agreed on the type of recommendation for 64% of compounds and differed on the remaining 36%. Such discrepancies may reflect differences in the agencies' evaluation frameworks, contributing to variation in patient access across the UK.

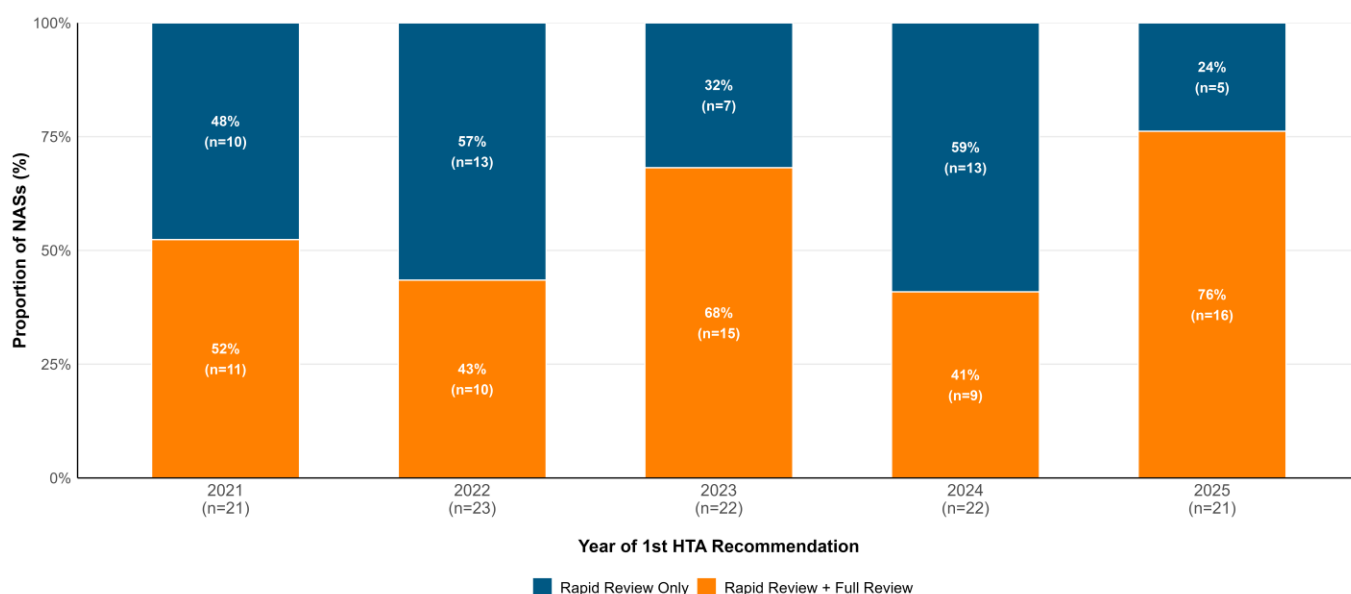
Figure 27. First HTA Recommendation Comparison of Common NASS (n=106) Reviewed by NICE and SMC
(HTA Recommendations Between 2021–2025)



Agreement between NICE and SMC: 64%; Disagreement: 36%
Note: each flow represents one HTA recommendation for one NAS
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Features of Ireland

Figure 28. Proportion of Rapid Reviews vs Full Reviews in Ireland (HTA Recommendations Between 2021-2025)

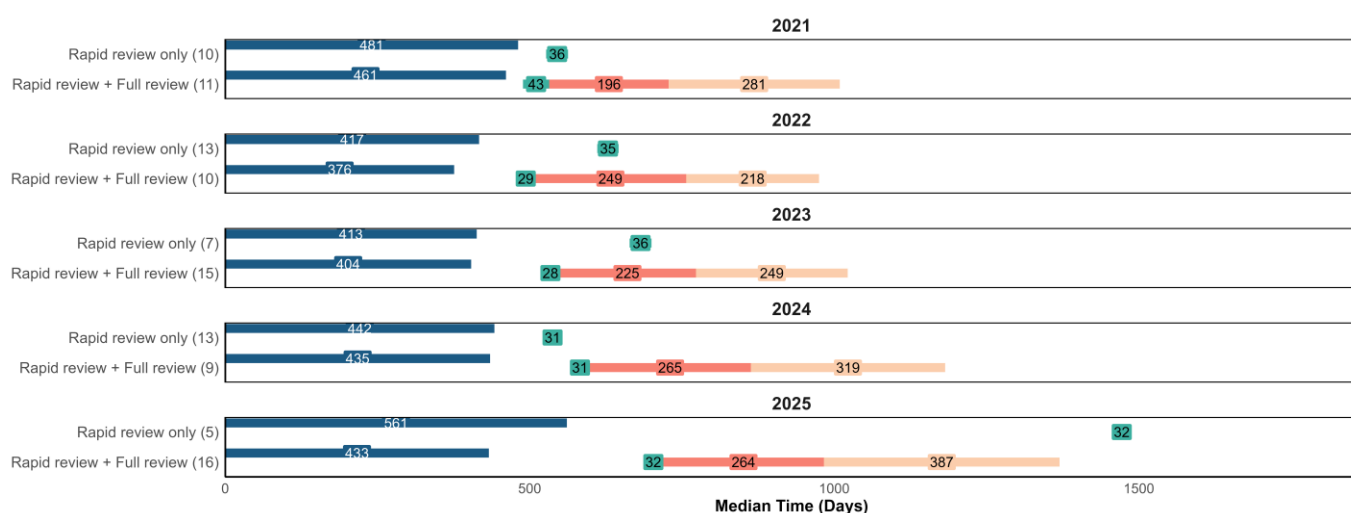


n = number of NASs

The primary objective of Rapid Reviews (RR) in Ireland is to assess new medicines to determine if they require a more comprehensive evaluation through a full HTA. If a full HTA is not needed, the RR provides a recommendation on reimbursement. The NCPE aims to complete a RR within four weeks, and in order to do this, some aspects of the full review are not part of the RR, such as evidence synthesis analyses and formal cost-effectiveness analyses. Following the RR, a full HTA may subsequently be recommended for those drugs for which additional information and/or analysis is required to inform a reimbursement recommendation. In some cases, a full HTA may not be needed if the Health Service Executive (HSE) can agree a suitable price reduction with the pharmaceutical company via confidential price negotiations. Between 2021 and 2025, 44% (48/109) products that were recommended by NCPE were approved for reimbursement via RR (**Figure 28**). 2025 presented the lowest proportion of RRs in the past 5 years, with 24% (5/21) of RRs.

Figure 29 illustrates the breakdown of rollout time for products recommended via RR compared with those requiring a full HTA review. Notably, where a full review was recommended, companies were required to submit additional information to the NCPE to support further analyses. This created an interval between the RR recommendation and the start of the full review (shown in pink in **Figure 29**) which contributed to the extended timeline. Notably, it is the applicant who is responsible for initiating a submission. In 2025, products recommended via RR alone had a longer median rollout time than those requiring a full review, reversing the pattern of the preceding four years. Based on five products, this should be interpreted with caution.

Figure 29. Breakdown of Rollout Time for NASs Recommendations in Ireland (Rapid vs Full HTA Reviews) (HTA Recommendation Between 2021 and 2025)

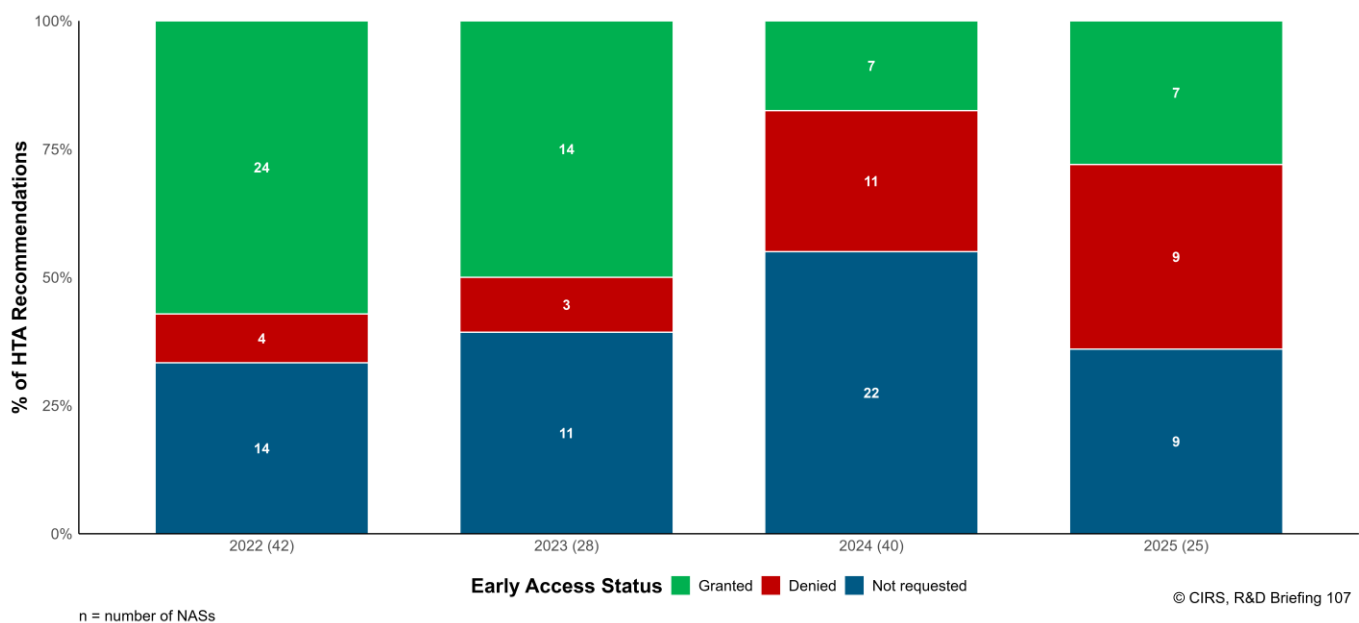


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n = number of NASs

Features of France

Figure 30. Proportion of NASs That Received an HTA Recommendation by Type of Early Access Application in France (HTA Recommendation Between 2022 and 2025)



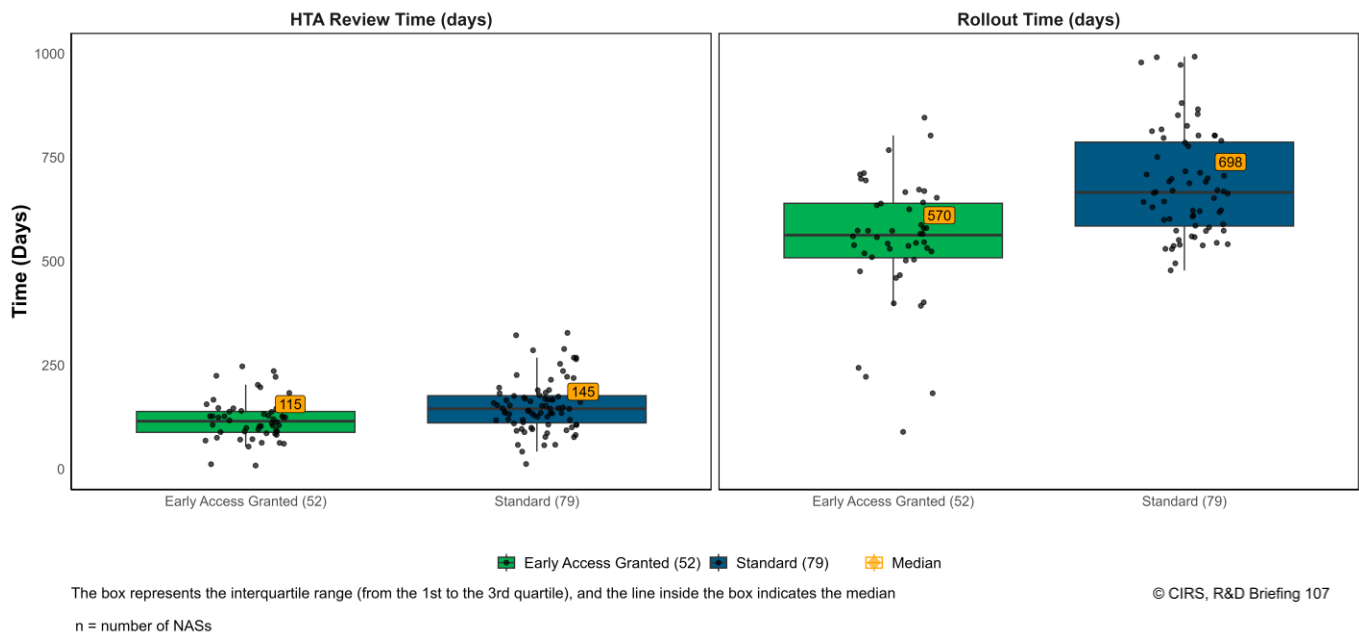
There was an increase in the proportion of NAS assessed in 2025 by HAS that had requested Early Access, compared to 2024.

Since 1st July 2021, HAS has evaluated and authorised medicines that are the subject of a request for coverage in the context of “Early Access”. Overall, Early Access is a mechanism that allows patients with unmet medical needs to benefit exceptionally and temporarily from certain drugs not recommended for reimbursement yet in a specific therapeutic indication.

Analysis of NASs evaluated by HAS highlights two trends (Figure 30). Firstly, the proportion of NASs assessed by HAS that had applied for Early Access decreased between 2022 and 2024 (67% (28/42) in 2022, 61% (17/28) in 2023, and 45% (18/40) in 2024) but increased in 2025 to 64% (16/25). Secondly, the proportion of Early Access applications that were denied rose sharply, from 14% (4/28) in 2022 and 18% (3/17) in 2023 to 61% (11/18) in 2024 and 56% (9/16) in 2025, suggesting a marked tightening of eligibility from 2024 onwards.

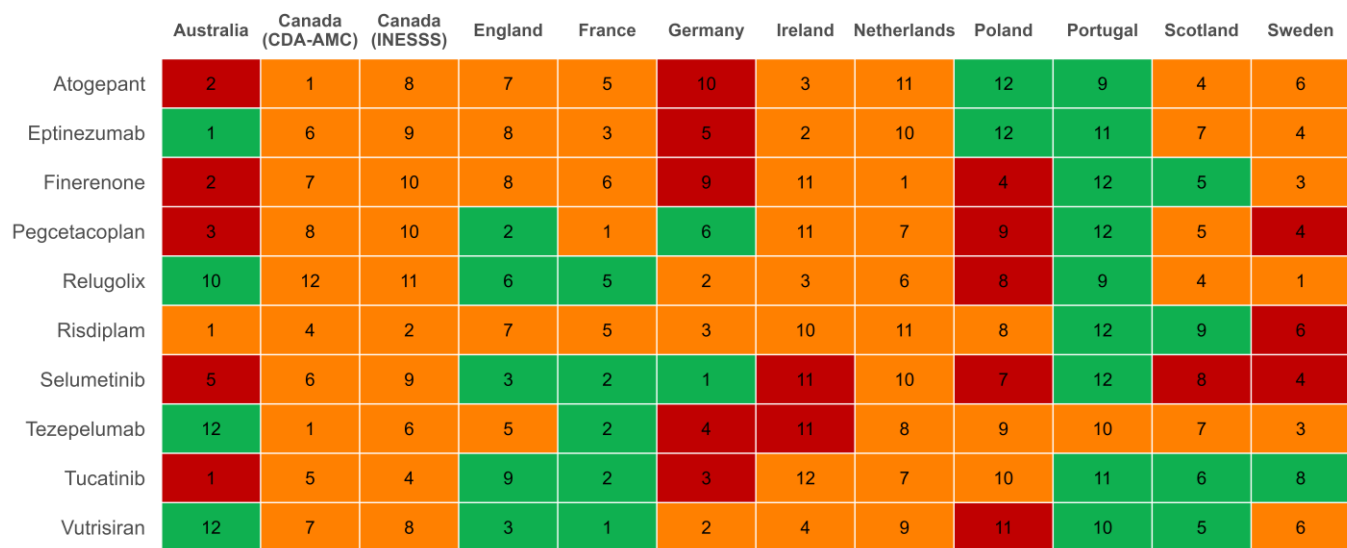
Figure 31 evaluates both the HTA review time and the rollout time for NASs that received an HTA recommendation in France, comparing products granted Early Access with those assessed through the standard pathway. The findings indicate that products with Early Access experienced shorter median HTA review times and faster rollout to market compared to standard NASs.

Figure 31. Rollout Time of NASs in France (Early Access Granted vs. Standard) (HTA Recommendation Between 2022 and 2025)



Common Compounds Across 12 Jurisdictions

Figure 32. First HTA Recommendation Comparison of Common NASs (n=10) Reviewed by 12 Agencies (HTA Recommendations Between 2021-2025)



HTA Outcome ■ Positive ■ Positive with restrictions ■ Negative

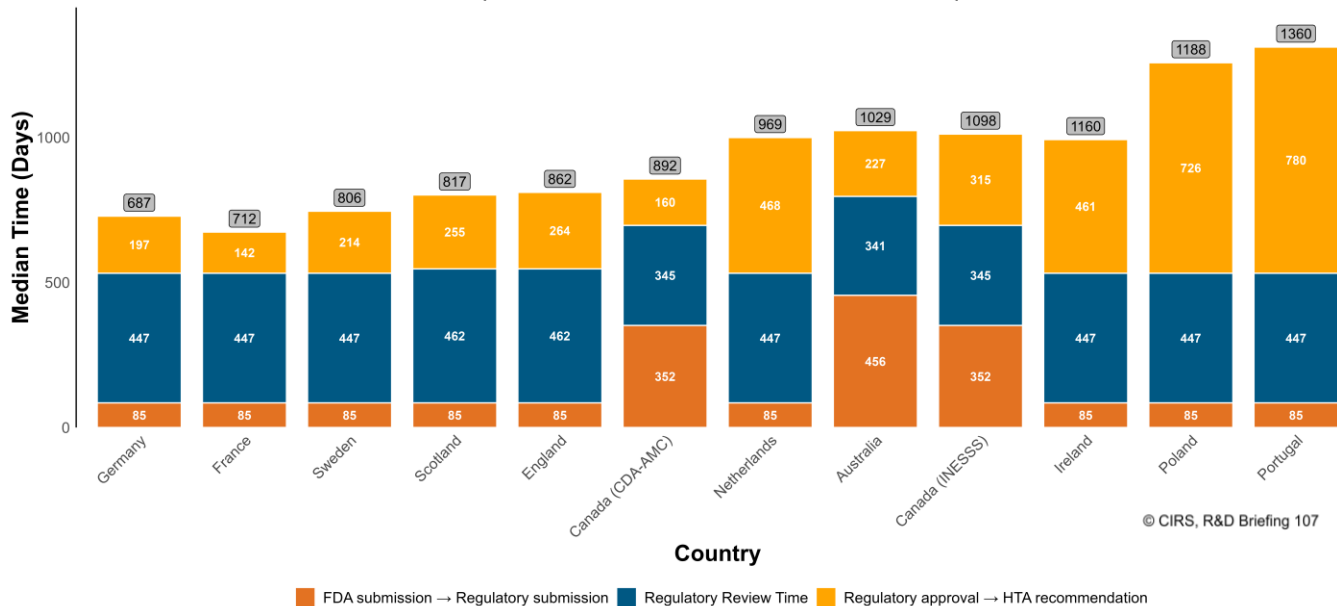
(n) = chronological order in which the HTA recommendations were published

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Between 2021 and 2025, ten NASs received first HTA recommendations in all 12 jurisdictions studied. We refer to these as "common compounds". **Figure 32** lists these ten compounds and uses a traffic light system to compare the HTA outcomes across the different jurisdictions. This visualisation highlights the variation in outcomes among the agencies. We also analysed the timing of the first HTA recommendation for each compound across the 12 agencies, ranking them from the earliest (1) to the latest (12). No jurisdiction was consistently first or last, as publication order varied by product. Notably, Australia, France, Germany and Sweden tended to be among the earlier jurisdictions, while Canada (INESSS), Ireland, Netherlands, Poland, and Portugal were more often later, with CDA-AMC, England, and Scotland in the middle.

Figure 33 presents the international rollout timeline for these common compounds, using the FDA submission date as a reference point. The data shows that regulatory approval submissions were typically first made to the EMA, followed by Canada and Australia. However, post-approval processes extended the time to HTA outcomes in some European countries, such as the Netherlands, Poland, and Portugal. Conversely, despite later regulatory submissions, Australia and Canada issued HTA outcomes sooner than some European jurisdictions due to faster post-approval timelines.

Figure 33. Breakdown of Rollout Time of Common NASs (n=10) Reviewed by 12 Agencies (HTA Recommendations Between 2021-2025)



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FDA submission → Regulatory submission Regulatory Review Time Regulatory approval → HTA recommendation

Note: Numbers in grey boxes represent the overall median time from FDA submission to HTA recommendation (days).

Definitions

Anti-cancer drugs

In this briefing, anti-cancer drugs refers to anti-cancer and immunomodulators (ATC code L).

Exclusion criteria (HTADock study)

Applications that are excluded from the study:

- Vaccines
- Any other application, where new clinical data were submitted
- Generic applications
- Those applications where a completely new dossier was submitted from a new company for the same indications as already approved for another company
- Applications for a new or additional name, or a change of name, for an existing compound (i.e., a 'cloned' application).

First assessment report

The first assessment report is the earliest assessment available. Note that for some drugs; for example, those with the same international nonproprietary names (INN), strength and presentation, are listed more than one time. The reasons may be twofold – consideration of the drug in more than one indication or re-assessment of the drug by the agency.

Health technology assessment (HTA)

For the purpose of this project, HTA refers to the assessment and appraisal of pharmaceuticals prior to reimbursement. The HTA process includes clinical assessment, economic assessment and an appraisal that results in either a coverage recommendation or recommendation.

HTA review time

Time (calendar days) calculated from the date of submission to the date of recommendation by the HTA agency. Note: The HTA recommendation refers to the recommendation at the national level.

New active substance (NAS)

A chemical, biological, biotechnology or radiopharmaceutical substance that has not been previously available for therapeutic use in humans and is destined to be made available as a 'prescription-only medicine', to be used for the cure, alleviation, treatment, prevention or in vivo diagnosis of diseases in humans; the term NAS also includes:

- An isomer, mixture of isomers, a complex or derivative or salt of a chemical substance previously available as a medicinal product but differing in properties with regard to safety and efficacy from that substance previously available.

- A biological or biotech substance previously available as a medicinal product, but differing in molecular structure, nature of source material or manufacturing process and which will require clinical investigation.
- A radiopharmaceutical substance that is a radionuclide or a ligand not previously available as a medicinal product. Alternatively, the coupling mechanism linking the molecule and the radionuclide has not been previously available.

Parallel review

Pharmaceutical companies submit evidence to the regulatory agency that prove the efficacy, safety, quality of the product. However, during the regulatory review process, companies submit dossiers to HTA bodies so that the two review steps can occur in parallel. Following the regulatory approval, HTA recommendation will be provided to companies for drug reimbursement. This sequence is available in Australia and Canada. In this briefing, a drug is identified as parallel if the HTA submission is earlier than regulatory approval.

Regulatory submission gap

Date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

Regulatory review time

Time (calendar days) calculated from the date of submission to the date of approval by the agency; this time includes agency and company time. Note: The EMA approval time includes the EU Commission time.

Rollout time

Date of submission at the regulatory agency to the date of HTA recommendation at the target jurisdiction (calendar days).

Sequential review

A regulatory review is conducted first to determine the benefit-risk profile of a new medicine, followed by the HTA review to assess the value of the medicine for a reimbursement decision. The regulatory-HTA sequence is seen at a national level in many countries, and also at a super-national level in Europe where a centralised regulatory decision made by the EMA is followed by jurisdictional HTA outcomes by member states.

Definitions

(Agency specific)

CDA-AMC - Request for reconsideration

The sponsor of a drug that is the subject of a draft recommendation and the drug programmes may file a request for reconsideration of the recommendation during the feedback period. The sponsor and drug programmes are entitled to have the draft recommendation reconsidered one time (this does not include situations where a revised draft recommendation has been issued after a request for reconsideration). A request for reconsideration can be made only on the grounds that the recommendation is not supported by the evidence that had been submitted or the evidence identified in the CDA-AMC review report(s).

MHRA - European Commission Decision Reliance Procedure (ECDRP)

From 1 January 2021, for a period of 3 years, the MHRA may rely on a decision made by the European Commission regarding the approval of a new marketing authorisation by the centralised procedure when evaluating an application for a Great Britain marketing authorisation.

MHRA - International Recognition Procedure (IRP)

The International Recognition Procedure (IRP) is a regulatory route introduced by the UK's MHRA on 1 January 2024, allowing marketing authorisation applications in the UK to rely on prior approvals from trusted reference regulators (such as the FDA, EMA, Health Canada, etc.). It aims to streamline the authorisation process by enabling a targeted MHRA assessment while maintaining regulatory independence. IRP has replaced the ECDRP.

HTA Orphan/Rare Disease-related Pathways

Country	HTA Orphan/Rare Disease-Related Pathways
Australia	Rule of rescue: A principle that favours listing of medicines with the following circumstances applied concurrently: • No alternative exists in Australia to treat patients with the specific circumstances of the medical condition meeting the criteria of the restriction. • The medical condition defined by the requested restriction is severe, progressive and expected to lead to premature death. • The medical condition defined by the requested restriction applies to only a very small number of patients. • The proposed medicine provides a worthwhile clinical improvement sufficient to qualify as a rescue from the medical condition. Life Saving Drugs Program (LSDP): LSDP provides fully subsidised access for eligible patients to expensive and life saving drugs for life threatening and rare diseases. The LSDP is separate to the PBS. All LSDP medicines have been considered by PBAC but not recommended for the PBS due in part to the high cost of the medicine. Highly specialised drugs: The Highly Specialised Drugs (HSD) Program provides access to specialised Pharmaceutical Benefits Scheme (PBS) medicines for the treatment of chronic conditions which, because of their clinical use and other special features, have restrictions on where they can be prescribed and supplied.
Canada	There is no separate CDA-AMC review process for drugs for rare diseases but in March 2016, the standard HTA recommendation framework was revised to make special consideration for these drugs. Note: The regulatory agency in Canada (Health Canada) does not currently have an orphan policy.
England	Highly specialised technologies (HST): A separate evaluation programme for medicines for very rare conditions, which applies a higher cost-effectiveness threshold than standard technology appraisals. Since April 2017, the HST threshold has been £100,000 per QALY gained. This can rise to a maximum of £300,000 per QALY through QALY weighting, which applies only when a treatment delivers substantial lifetime health gains. By comparison, the standard NICE threshold for technology appraisals was increased from £20,000-£30,000 to £25,000-£35,000 per QALY in April 2026.
France	Early Access: Since 1st July 2021, HAS can evaluate and authorise medicines that are requested for coverage under the "early access" provision. "Early access" is a mechanism that allows patients to benefit on an exceptional and temporary basis from certain drugs not authorised for a specific therapeutic indication. The following four conditions must be met: 1. The drug must be intended to treat serious, rare, or disabling diseases. 2. No appropriate treatment must be available. 3. Implementation of the treatment cannot be postponed. 4. The medicinal product must be presumed to be innovative, especially in comparison to a possibly clinically relevant comparator. Early access applies to drugs either awaiting reimbursement approval or lacking marketing authorisation. In this scenario, the French National Agency for Medicines and Health Products Safety (ANSM) must assent to its efficacy and safety based on the results of therapeutic trials before HAS makes a decision.
Germany	For orphan drugs, additional therapeutic benefit is considered to be proven at marketing authorisation as long as the annual statutory health insurance (SHI) expenditure for the entire population is below EUR 30 million. IQWiG only assesses information provided by the companies on patient costs and patient numbers. The IQWiG outcomes for orphan drugs are categorised as "positive" within this briefing. Once the EUR 30 million threshold is exceeded, companies are required to submit data on additional therapeutic benefit and orphan drugs are evaluated and prices renegotiated in the same manner as for all other drugs. The assessment of orphan drugs is conducted by G-BA, and the approach for evidence appraisal is similar to the non-orphan assessed by IQWiG. However, the orphan assessment report only determines the extent of additional benefit, and the categories 'no additional benefit' or 'less benefit' are not applicable. Under the GSAV law implemented in July 2019, additional real-world evidence can be requested by G-BA at the initial assessment for drugs with conditional approval and all orphan drugs.
Poland	There is no separate AOTMiT process but there are ongoing plans to introduce a separate procedure for rare and ultra-rare diseases such as the introduction of the multi-criteria decision analysis (MCDA) method (Polityka Lekowa Państwa 2018–2022).
Scotland	Orphan medicine: A medicine with EMA designated orphan status (conditions affecting fewer than 2,500 people in a population of 5 million) or a medicine to treat an equivalent size of population irrespective of whether it has orphan status. Ultra-orphan medicine: To be considered as an ultra-orphan medicine all criteria listed should be met: • the condition (typically a recognised distinct disease or syndrome) has a prevalence of 1 in 50,000 or less in Scotland • the medicine has a Great Britain (GB) orphan marketing authorisation from the Medicines and Healthcare products Regulatory Agency (MHRA) • the condition is chronic and severely disabling, and • the condition requires highly specialised management. SMC uses the description of the orphan condition within the MHRA Orphan Register. Submissions for medicines that are validated as ultra-orphan according to this definition will be assessed by SMC and will then be available to prescribers for a period of up to three years while further clinical effectiveness data are gathered. After this period, the company will be asked to provide an updated submission for reassessment and SMC will make a recommendation on the routine use of the medicine in NHSScotland. For medicines used at end of life and for very rare conditions, companies may ask for the medicine to be considered at a Patient and Clinician Engagement (PACE) meeting. This additional step allows SMC to hear more evidence from patient groups and clinicians on the added value of a medicine, which may not always be captured in the company's submission. The output from a PACE meeting is a major factor in SMC recommendation-making. Companies can also submit or improve a Patient Access Scheme (PAS), which can help to improve the value for money of the medicine.
Sweden	There is no separate review process in Sweden but TLV can consider a higher cost-effectiveness threshold based on unmet need, severity of condition, and limited budget impact due to small populations.

Facilitated Regulatory Pathways

Country	Facilitated Regulatory Pathways
Australia	TGA Priority: A formal mechanism for faster assessment of vital and life-saving medicines for severe, debilitating or life-threatening diseases, to address unmet medical needs and where a high therapeutic benefit can be expected. TGA Provisional Approval: Time-limited provisional registration for certain promising new medicines where the benefit of early availability of the medicine outweighs the risk inherent in the fact that additional data are still required.
Canada	Health Canada Priority: A fast-track status for medicines for severe, debilitating or life-threatening diseases; to address unmet medical needs and where a high therapeutic benefit can be expected. Health Canada Conditional: Authorisation to market a new promising drug with the condition that the sponsor undertakes additional studies to verify the clinical benefit.
Europe	EMA accelerated assessment: A process designed to expedite products of major interest in terms of public health and therapeutic innovation. EMA conditional Approval: Regulation allowing drugs fulfilling unmet medical needs for severe, life-threatening or rare diseases to be approved with limited clinical safety or efficacy data, provided a positive benefit-risk balance.

R&D Briefing 107



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About CIRS

The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to maintain a leadership role in identifying and applying scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes in developing and facilitating access to pharmaceutical products.

CIRS provides an international forum for industry, regulators, HTA and other healthcare stakeholders to meet, debate and develop regulatory and reimbursement policy. It is governed and operated by Clarivate for the sole support of its members' activities. The organisation has its own dedicated management and advisory boards, and its funding is derived from membership dues, related activities, special projects and grants.

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