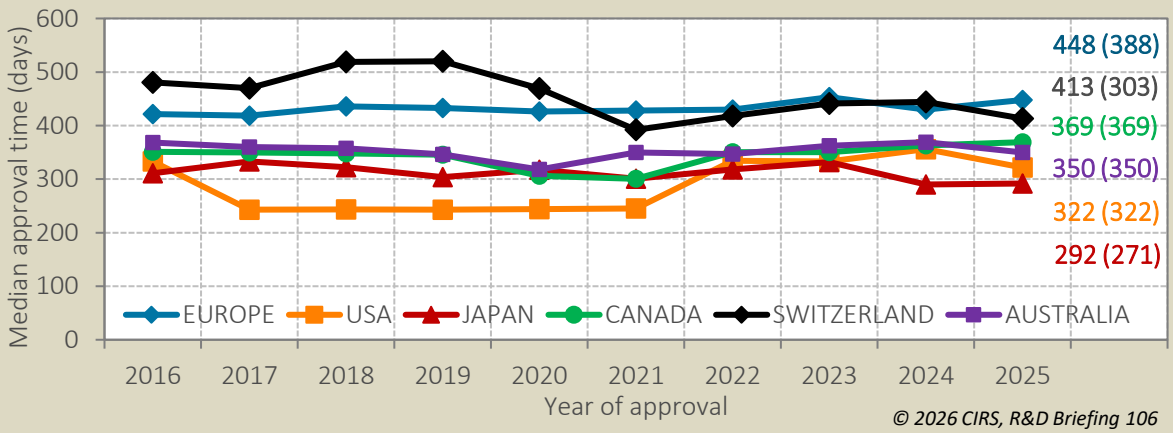
New drug approvals by six major authorities 2016-2025:

Trends in an evolving regulatory landscape

This R&D Briefing presents the results from the Centre for Innovation in Regulatory Science (CIRS) annual analysis of new active substance (NAS) approvals by six major regulatory agencies: the European Medicines Agency (EMA), the US Food and Drug Administration (FDA), the Japan Pharmaceuticals and Medical Devices Agency (PMDA), Health Canada, Swissmedic and the Australian Therapeutic Goods Administration (TGA). The analysis focuses on 2025, while also retrospectively examining trends from 2016 to 2025. Although median approval times can be a marker of agency performance and the time it takes to make medicines available to patients, other factors must be considered as illustrated in the infographic below.

Contents

Median approval timelines for new active substances across six regulatory authorities (2016–2025)



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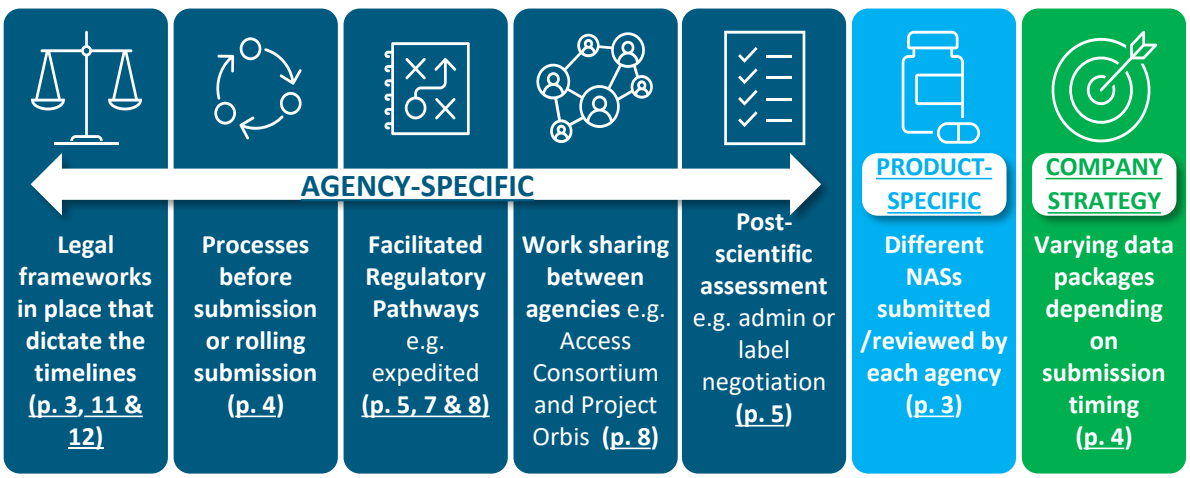
Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. N1 = median approval time for products approved in 2025; (N2) = median time from submission to the end of scientific assessment (see p. 24) for products approved in 2025.

Differences in median approval time can be attributed to several factors, including agency-specific, product-specific or related to the company, such as its strategies. Each factor is explored further in the infographic below and on the linked pages.



Key messages

- In 2025, FDA granted the highest number of NAS approvals (50), followed by Health Canada (44), TGA (42), PMDA (40), EMA (39) and Swissmedic (34) (Fig. 1). While FDA approved more products than its peers over the past decade, not all of them were internationalised promptly (see p. 4).
- In 2025, PMDA had the shortest median approval time (292 days), followed by FDA (322 days), TGA (350), Health Canada (369), Swissmedic (413) and EMA (448)(Fig. 2).
- In 2025, FDA had the shortest median submission gap at 0 days, followed by EMA (69 days), Swissmedic (569 days), Health Canada (670 days), TGA (700 days) and PMDA (807 days). Submission gap variability also differed markedly across the authorities, with IQRs ranging from 0 days (FDA) to 1326 days (PMDA). EMA had the second-narrowest IQR at 229 days (Fig. 3).
- In 2025, median submission gaps were generally longer for 'Non-Top Companies' compared with 'Top Companies' for most agencies. The largest difference was observed for Health Canada (457 days), followed by Swissmedic (434 days), TGA (330 days), EMA (37 days), whereas PMDA showed a distinct pattern, with the median submission gap increasing markedly for Top Companies while decreasing for Non-Top Companies. The reduction among Non-Top Companies may partly reflect changes in the composition of approvals, including a greater representation of Japan-headquartered companies in 2025 (Fig. 4).
- In 2025, the use of expedited review pathways for NAS approvals varied notably across agencies. FDA had the highest proportion at 56%, followed by PMDA (53%), Health Canada (25%), Swissmedic (18%), TGA (10%) and EMA (5%). PMDA's proportion of expedited approvals increased considerably from 34% in 2024 to 53% in 2025. Between 2021-2025, the use of expedited pathways was fairly consistent across the agencies, except for the FDA, which showed a declining trend from 71% in 2021 to 56% in 2025 (Fig. 5).
- In 2025, expedited reviews had shorter median approval times than standard reviews across all six authorities. EMA and Health Canada shared the shortest median for expedited reviews (235 days), while TGA had the longest (306 days). EMA showed the largest difference between review types in 2025, with expedited approvals being 217 days faster than standard ones (Fig. 6).
- Between 2021 and 2025, anti-infective therapies had the shortest overall median approval time across the six authorities (273 days), followed by therapies for alimentary and metabolism (328 days), anti-cancer and immunomodulators (353 days), blood-related conditions (365 days), and nervous system disorders (414 days) (Figs. 7 and 8).
- The use of facilitated regulatory pathways (FRPs, see p. 21 for definitions) increased for all authorities between 2021–2025 compared to 2016–2020. FDA was the authority that most frequently used FRPs between 2021–2025, with 75% of NAS approvals involving at least one FRP, followed by Swissmedic (68%), TGA (62%), Health Canada (55%), PMDA (42%) and EMA (36%) (Fig. 9).
- In 2025, the proportion of NAS approvals granted by conditional/temporary/provisional pathways was 24% for FDA, 23% for EMA, 16% for Health Canada, 6% for Swissmedic, 5% for TGA and 3% for PMDA (Fig. 10).
- In 2025, the proportion of NAS approvals with an orphan designation was high across all authorities, with 62% for Swissmedic, 54% for FDA, 53% for PMDA, 38% for EMA and 36% for TGA (Fig. 12). In 2025, PMDA had the fastest median approval time for orphan products at 269 days, followed by FDA (322 days), TGA (373 days), EMA (452 days) and Swissmedic (452 days) (Fig. 13).
- The number of NASs approved by all six authorities increased from 37 in 2016–2020 to 52 in 2021–2025. Alongside the expansion in global approvals, submission sequencing has shifted. PMDA submissions are now occurring earlier relative to other agencies, as reflected by larger median submission gaps for Health Canada, Swissmedic and TGA. (Fig. 14).
- From 2021 to 2025, EMA median approval times for NASs remained consistent, ranging from 428 to 448 days. In 2025, the median CHMP assessment accounted for 49% of the overall median, followed by company response (30%), European Commission decision (13%), and validation (5%) (Figs. 15 and 16).
- In 2025, 74% of NAS approvals at the FDA were granted within the first review cycle, the highest proportion observed over 2021-2025. In 2025, first-cycle approvals without major amendments had the shortest approval timelines, while multi-cycle approvals often exceeded 500 days (Figs. 17 and 18).
- While the overall inclusion of patient experience data (PED) in FDA NAS approvals decreased in 2025 to 72% compared with 84% in 2024, levels remain broadly aligned with earlier years. The use of multiple sources of PED - alongside sponsor-submitted data - has increased from 12% in 2021 to 20% in 2025, pointing to a more proactive and diversified approach to integrating patient evidence.(Fig. 19).

See agency-specific infographics for 2025 snapshots:

EMA	FDA	PMDA	Health Canada	Swissmedic	TGA
p. 15	p. 16	p. 17	p. 18	p. 19	p. 20

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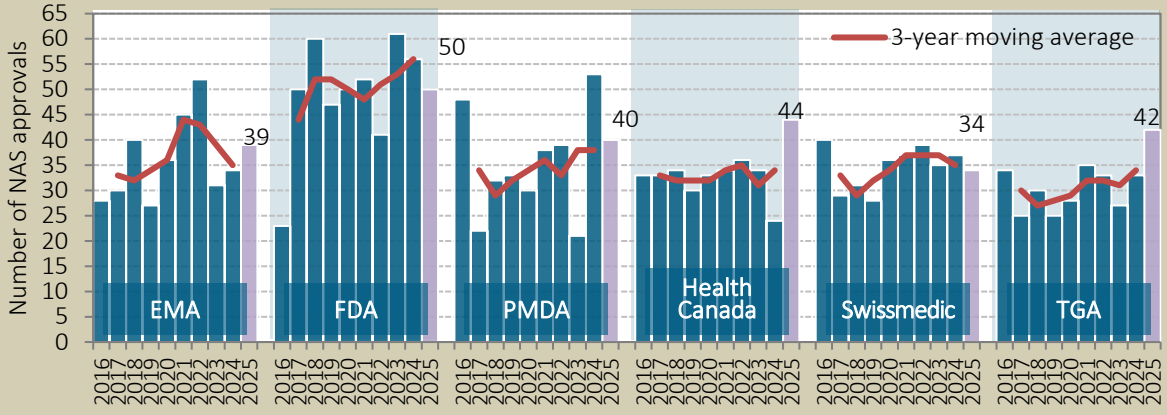
Overall approvals

Figure 1. Trends in NAS approvals across six regulatory authorities (2016–2025)



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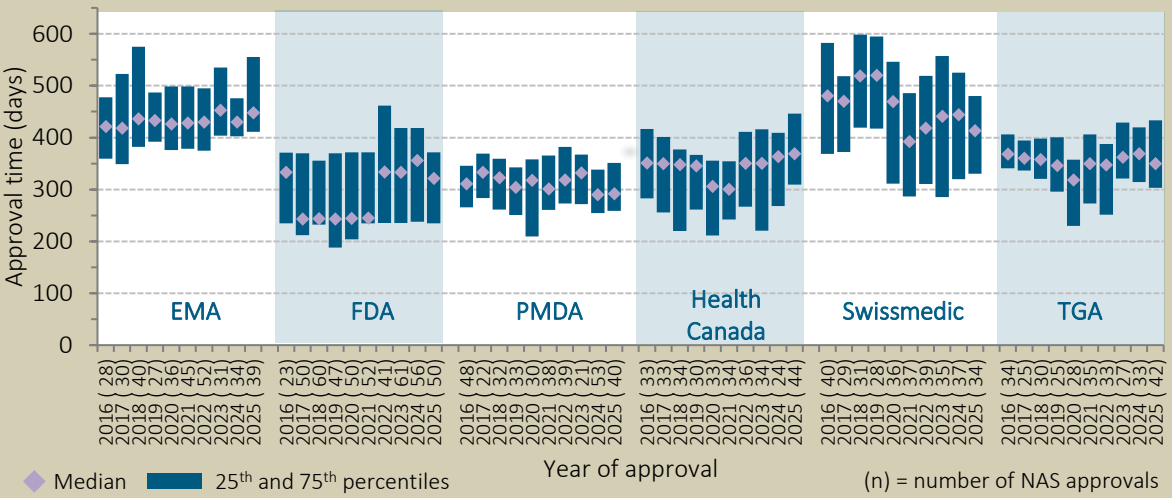
In 2025, FDA approved the highest number of NASs, with 50 approvals, followed by Health Canada (44), TGA (42), PMDA (40), EMA (39) and Swissmedic (34) (Fig. 1). While FDA consistently approved more NASs than its peers over the past decade, not all of these products were internationalised promptly, and some took a considerable length of time to reach other markets (see p. 4).

Comparing the first and second halves of the decade (2016–2020 vs. 2021–2025), the largest relative increase in NAS approvals was observed at EMA with 25%, followed by TGA (20%) and PMDA (16%). More moderate growth was seen at FDA (13%) and Swissmedic (11%), while Health Canada recorded a comparatively limited increase (6%).

Variation in the number of NAS approvals across authorities likely reflects a range of factors, including differences in company submission strategies, market size, unmet medical needs, expected review timelines, and the uptake of risk-based or collaborative/work-sharing review pathways.

Figure 2. Approval time variability for NAS approvals across six regulatory authorities (2016–2025)



Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.

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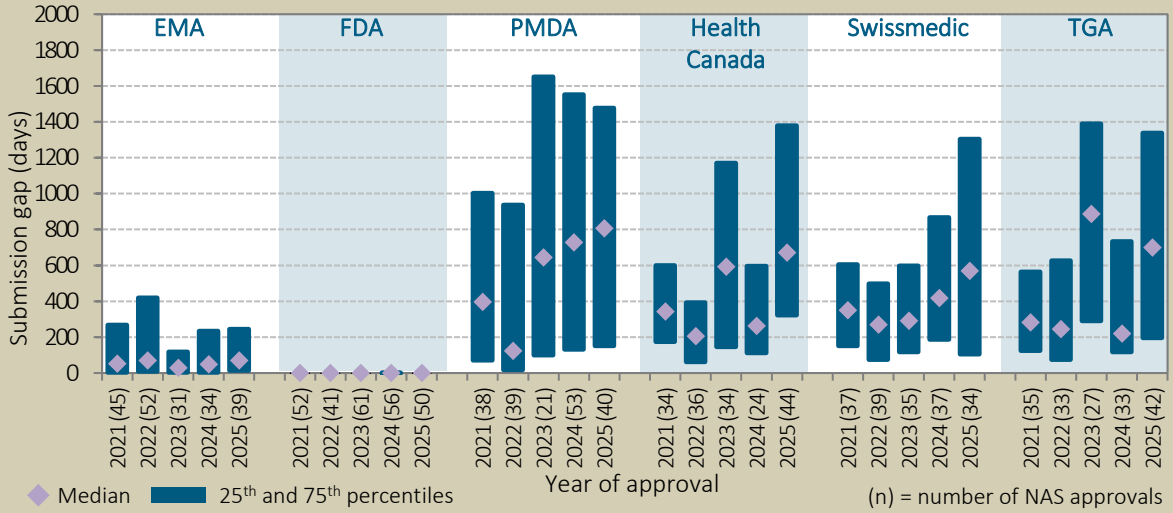
In 2025, PMDA had the shortest median approval time, at 292 days (interquartile range [IQR] 79 days). EMA had the longest median at 448 days (IQR 132), resulting in a 156-day difference between the two authorities. FDA had the second shortest median approval time with 322 days (IQR 124), followed by TGA (350; IQR 118), Health Canada (369; IQR 124) and Swissmedic (413; IQR 137) (Fig. 2).

While overall approval times varied across the six authorities, the difference was less pronounced when comparing the median time from submission to the end of scientific assessment. In fact, there was a 117-day gap between PMDA and EMA when approval times were calculated this way (see p. 1; definitions on p. 24).

Submission gap

Figure 3. Submission gap variability for NAS approvals across six regulatory authorities (2021–2025)



Submission gap is calculated as the time from the date of submission to the first regulatory authority to the date of regulatory submission to the target regulatory authority.

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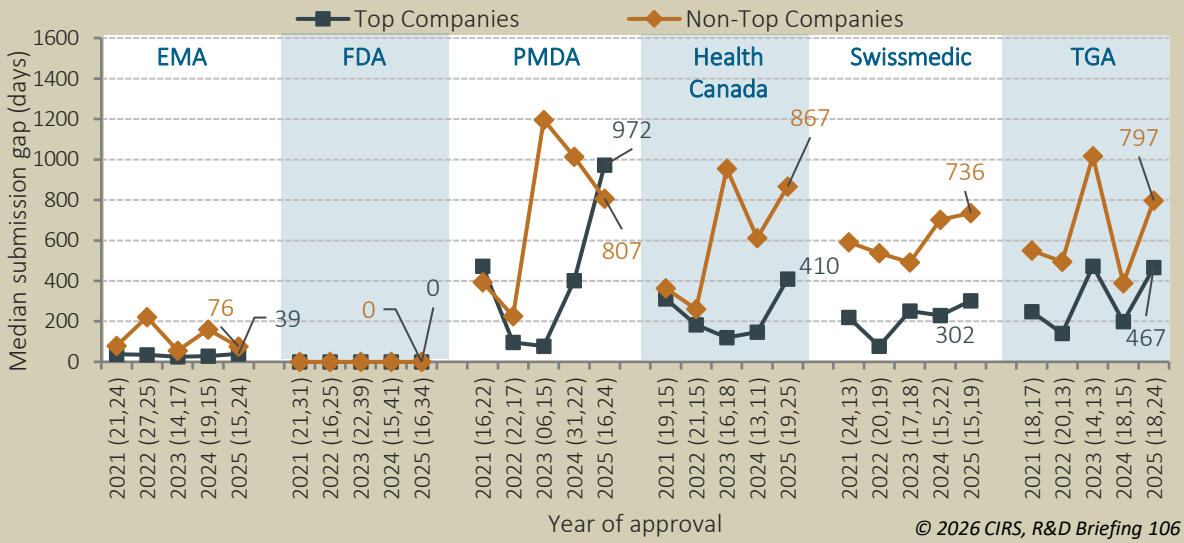
In 2025, FDA had the shortest median submission gap at 0 days, followed by EMA (69 days), Swissmedic (569 days), Health Canada (670 days), TGA (700 days) and PMDA (807 days). Submission gap variability also differed markedly across the authorities, with IQRs ranging from 0 days (FDA) to 1326 days (PMDA). EMA had the second-narrowest IQR at 229 days (Fig. 3).

Swissmedic's IQR has expanded substantially over the recent years, reaching 1197 days in 2025 and representing the second widest spread among the six agencies. In turn, IQRs for TGA and Health Canada were similar to those observed in 2023, at 1142 days and 1057 days, respectively. These shifts across agencies could indicate evolving company strategies, such as the increasing use of collaborative and work-sharing pathways in some regions, while in others, they may be influenced by company size, with submissions from small companies often correlating with longer submission gaps.

Figure 4. Trends in submission gap by company size in NAS approvals across six regulatory authorities (2021–2025)



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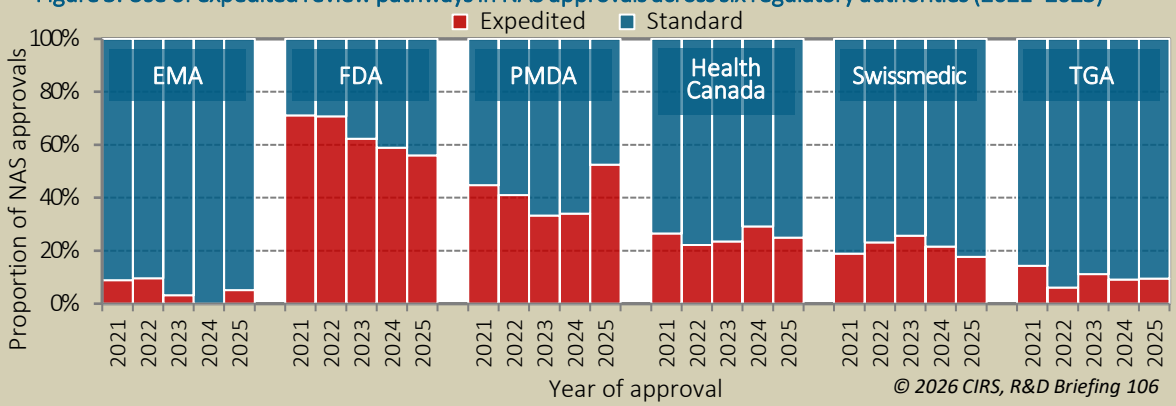
***Submission gap** is calculated as the time from the date of submission at the first regulatory authority to the date of regulatory submission to the target regulatory authority. **Top companies** were defined as pharmaceutical companies with R&D expenditures ≥ 3 billion USD in 2024, as reported in Pharm Exec Top 50 Companies (2025). **(n1,n2)** = (number of NAS approvals granted to Top Companies, number of NAS approvals granted to Non-Top Companies).*

In general, median submission gaps were longer for 'Non-Top Companies' compared with 'Top Companies'. In 2025, the largest median difference between these two groups was observed for Health Canada (457 days), followed by Swissmedic (434 days), TGA (330 days), EMA (37 days), whereas PMDA showed a negative difference of 165 days (Fig. 4). These findings suggest that company size and resources may influence the ability to coordinate early submissions across agencies. PMDA appears to follow a distinct pattern, with the median submission gap increasing markedly for Top Companies while decreasing for Non-Top Companies. The reduction among Non-Top Companies may partly reflect changes in the composition of approvals, including a greater representation of Japan-headquartered companies in 2025.

Expedited review pathways

Figure 5. Use of expedited review pathways in NAS approvals across six regulatory authorities (2021–2025)

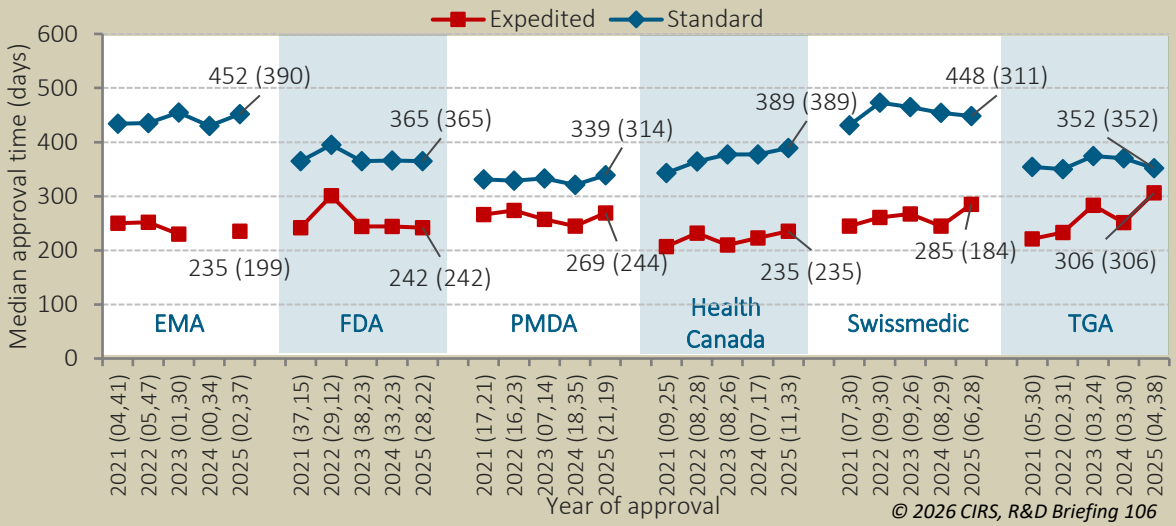


__Expedited review__ refers to EMA's __'Accelerated Assessment'__. For FDA, Health Canada, TGA, and PMDA, it refers to __'Priority Review'__. For Swissmedic, expedited review includes __'Fast-track procedure' and 'Temporary Authorisation procedure'__. For the purposes of this analysis, __ex officio temporary authorisations were considered to have been reviewed under the standard procedure__.

The use of expedited review pathways for NAS approvals varied notably across authorities in 2025. FDA had the highest proportion at 56%, followed by PMDA (53%), Health Canada (25%), Swissmedic (18%), TGA (10%) and EMA (5%) (Fig. 5). The overall proportion of expedited approvals remained similar to 2024 outcomes across most authorities, except for PMDA, which increased from 34% to 53%. Across 2021–2025, proportions remained broadly stable for most agencies, whereas FDA showed a decline from 71% to 56%.

Although EMA approved two NASs through an accelerated assessment in 2025, 12 additional requests were identified. Two were initially accepted and then reverted to standard review after major objections were raised that compromised the feasibility of maintaining an accelerated timeline. The remaining requests were not granted because they were not considered of major public health interest.

Figure 6. Trends in median approval time by review type in NAS approvals across six regulatory authorities (2021–2025)



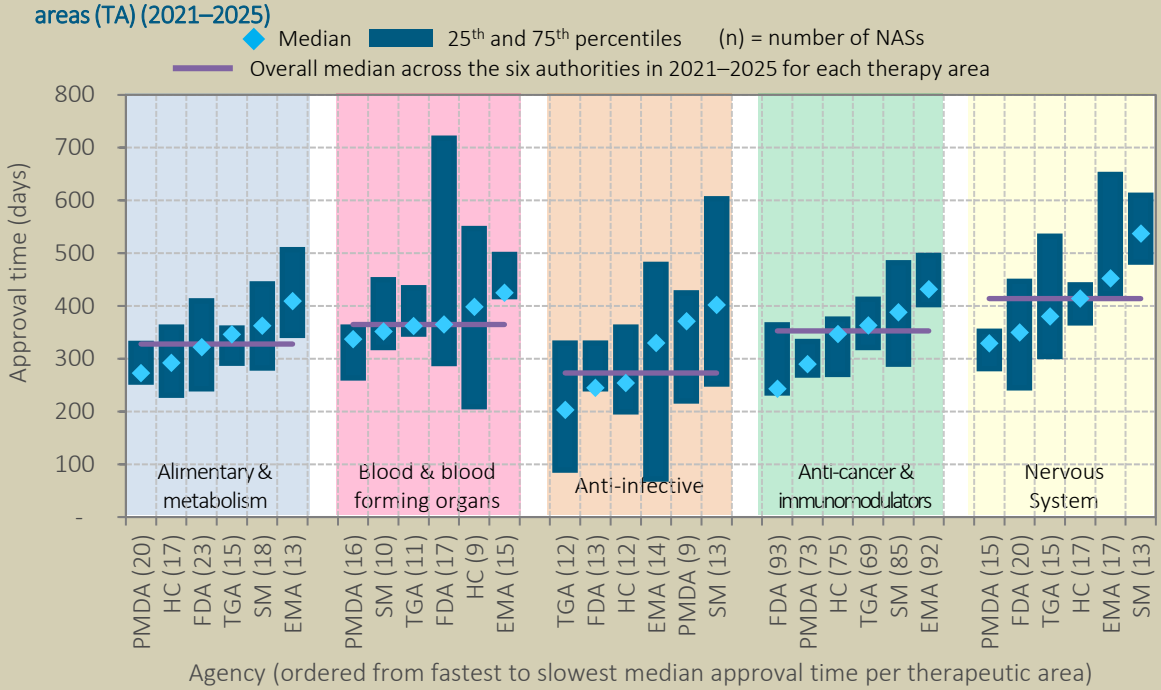
__Approval time__ is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. __N1:__ Overall approval time for 2025. __(N2):__ Time from submission until the end of scientific assessment. __Expedited review__ refers to EMA's __'Accelerated Assessment'__. For FDA, Health Canada, TGA, and PMDA, it refers to __'Priority Review'__. For Swissmedic, expedited review includes __'Fast-track procedure' and 'Temporary Authorisation procedure'__. For the purposes of this analysis, __ex officio temporary authorisations were considered to have been reviewed under the standard procedure__. __(n1,n2):__ (number of NAS approvals reviewed through an expedited review, number of NAS approvals reviewed through a standard review).

Median approval times were consistently shorter for expedited reviews compared to standard reviews across all six authorities in 2025, a pattern that has been sustained over the past five years. EMA and Health Canada shared the shortest median approval time for expedited reviews at 235 days, while TGA had the longest at 306 days (Fig. 6).

In 2025, the largest difference between expedited and standard medians was observed at EMA (217 days), followed by Swissmedic (163 days), Health Canada (154 days), FDA (123 days), PMDA (70 days), and TGA (46 days). At EMA, the difference extended beyond scientific assessment, as expedited NAS approvals had a 36-day interval between the median approval time and the median time to the end of scientific assessment, whereas standard reviewed NAS approvals had 62 days for the same interval, suggesting a shorter authorisation process when expedited review is used. A similar pattern was observed for Swissmedic.

Therapeutic areas

Figure 7. Approval time variability for NAS approvals across six regulatory authorities by top five therapeutic areas (TA) (2021–2025)



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Therapy areas relate to the WHO ATC codes. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.

Between 2021 and 2025, anti-infective therapies had the shortest overall median approval time across the six authorities (273 days), followed by therapies for alimentary and metabolism (328 days), anti-cancer and immunomodulators (353 days), blood-related conditions (365 days), and nervous system disorders (414 days) (Fig. 7 & 8). Across the therapeutic areas, a higher proportion of expedited review was associated with shorter overall median approval times, suggesting that differences in pathway utilisation were a key driver of these observed variations.

Compared with previous briefings (R&D 93, 81, 85 and 88), the gap between anti-infective therapies and other therapeutic areas has widened, likely due to the expedited review of NASs targeting COVID-19, RSV, CMV, and multidrug-resistant bacterial infections.

Alimentary and metabolism therapies remained the second fastest-reviewed therapeutic area, with anti-cancer and immunomodulators ranking third, which may indicate re-prioritisation of unmet medical needs.

Figure 8. Overall median approval time and proportion of expedited-reviewed NAS approvals by top five TAs across six regulatory authorities (2021–2025)

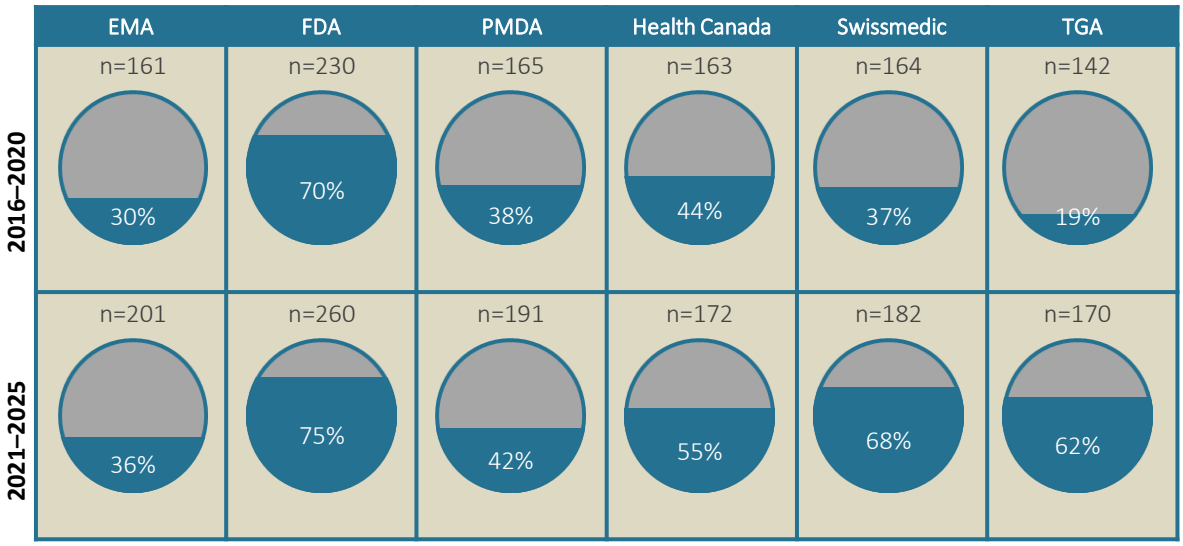
© 2026 CIRS, R&D Briefing 106	Alimentary and metabolism	Blood and blood forming organs	Anti-infective	Anti-cancer and immuno-modulators	Nervous system
Approval time in days (proportion of expedited reviewed approvals)					
EMA	409 (15%)	425 (0%)	330 (14%)	432 (7%)	452 (0%)
FDA	322 (70%)	365 (53%)	245 (92%)	243 (70%)	350 (60%)
PMDA	273 (70%)	337 (56%)	371 (56%)	290 (48%)	329 (27%)
Health Canada	292 (53%)	398 (44%)	254 (58%)	347 (16%)	414 (12%)
Swissmedic	363 (22%)	352 (30%)	402 (31%)	388 (27%)	537 (0%)
TGA	346 (0%)	362 (9%)	203 (33%)	363 (9%)	380 (7%)
Overall	328 (42%)	365 (33%)	273 (47%)	353 (30%)	414 (20%)

***Therapeutic areas** relate to the WHO ATC codes. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. **Expedited review** refers to EMA's **'Accelerated Assessment'**. For FDA, Health Canada, TGA, and PMDA, it refers to **'Priority Review'**. For Swissmedic, expedited review includes **'Fast-track procedure' and 'Temporary Authorisation procedure'**. For the purposes of this analysis, **ex officio temporary authorisations were considered to have been reviewed under the standard procedure**.*

Focus on facilitated regulatory pathways (FRPs)

Over the last five years (2021–2025), the usage of facilitated regulatory pathways (FRPs, see p. 21 for definitions) has increased for all agencies compared with the beginning of the decade (2016–2020) (Fig. 9). FDA was the authority that most frequently used FRPs between 2021–2025, with 75% of NAS approvals involving at least one FRP, followed by Swissmedic (68%), TGA (62%), Health Canada (55%), PMDA (42%) and EMA (36%). TGA was the authority that had the biggest increase in terms of the percentage of NAS approvals with FRPs, which reflects the implementation of TGA's five FRPs (starting in 2017 with Priority review, Provisional approvals, Comparable overseas regulators (COR) review, Access Consortium, and Project Orbis). The proportion of NAS approvals with an FRP remained largely similar across the two periods for EMA, FDA and PMDA.

Figure 9. Proportion of NAS approvals across six regulatory authorities that benefited from at least one facilitated regulatory pathway (2016–2020 vs 2021–2025)



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In 2025, the proportion of NAS approvals granted by conditional/temporary/provisional pathways was 24% for FDA, 23% for EMA, 16% for Health Canada, 6% for Swissmedic, 5% for TGA and 3% for PMDA (Fig. 10). The number of conditional/accelerated/provisional approvals has generally fluctuated year on year between 2021–2025; however, Swissmedic and TGA show indications of a declining trend. In general, these types of approval pathways were faster than the overall median approval time (Fig. 11, on p. 8), which may be due to the use of expedited pathways.

Figure 10. Number of NAS approvals granted through a conditional, temporary or provisional pathway across the six regulatory authorities (2016–2025)

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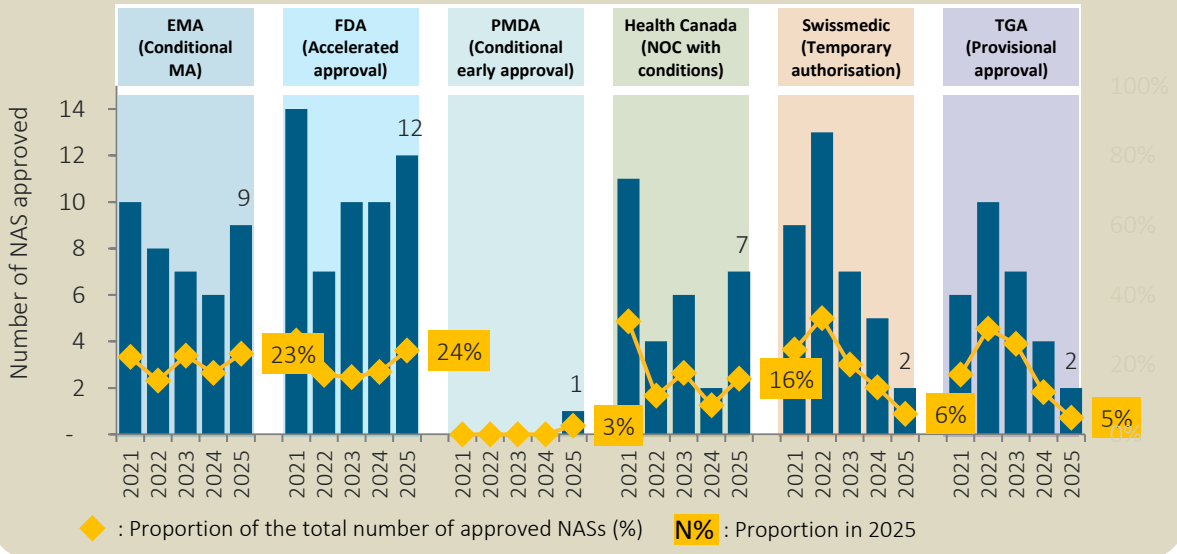
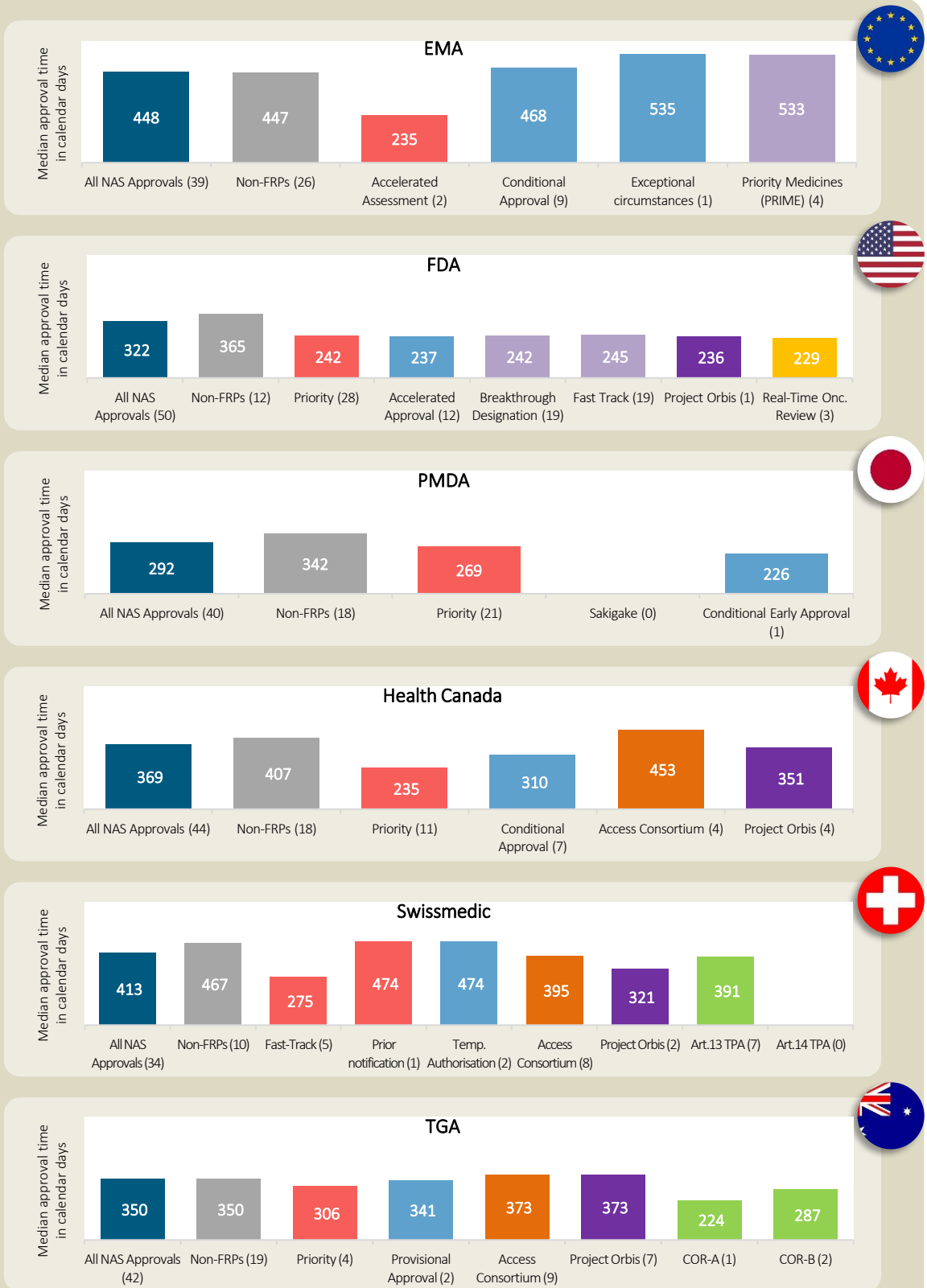


The 2025 NAS median approval times for the different FRPs are illustrated on the next page (Fig. 11).

Focus on facilitated regulatory pathways (FRPs) *(cont.)*

Figure 11. FRPs median approval timelines across six regulatory authorities — Focus on 2025



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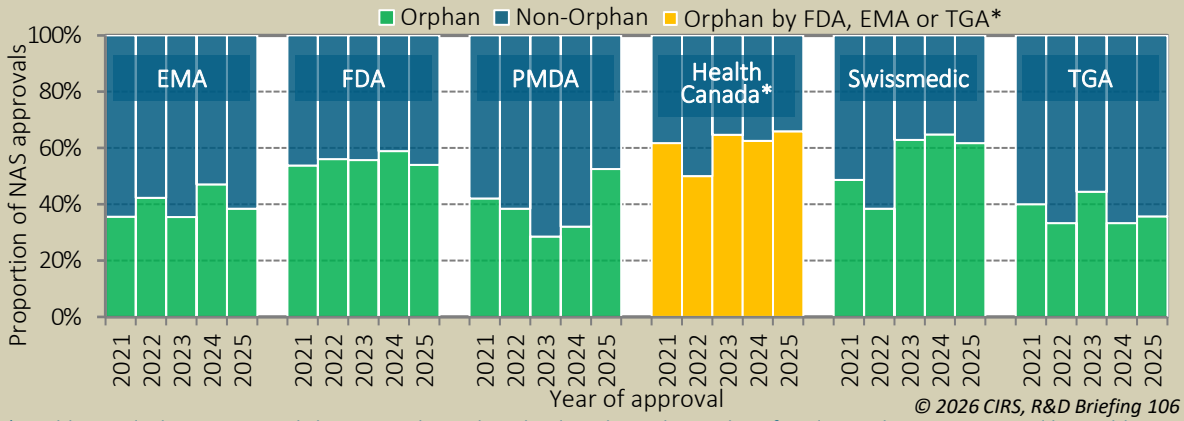
(n) = number of NASs

For FRP definitions, see p.21.

Orphan designations

Figure 12. Proportion of NAS approvals by orphan designation across six regulatory authorities (2021–2025)



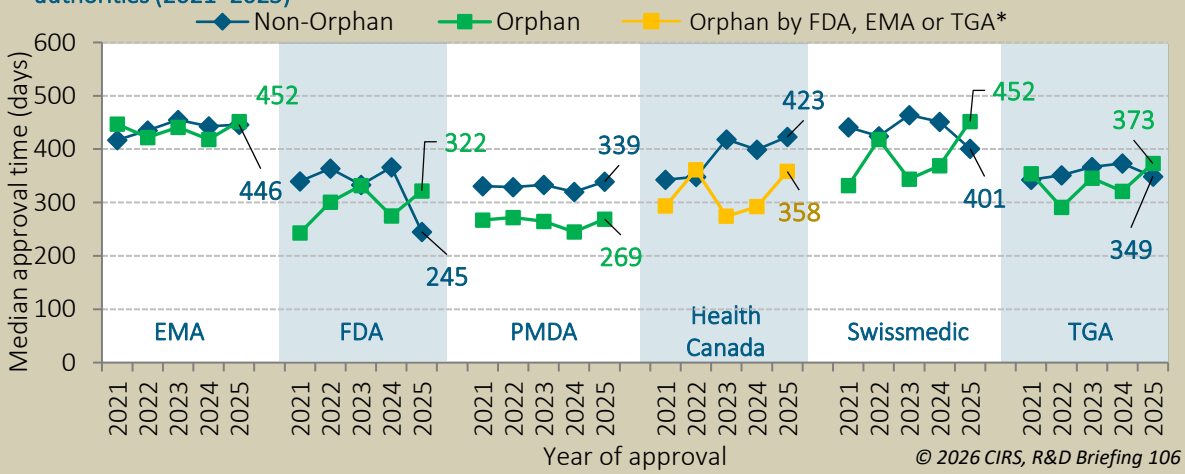
** Health Canada does not currently have an orphan policy; this data shows the number of medicines that were approved by Health Canada that were classified as orphan by either FDA, EMA or TGA.*

In 2025, the proportion of NAS approvals with an orphan designation was high across all authorities, with 62% for Swissmedic, 54% for FDA, 53% for PMDA, 38% for EMA and 36% for TGA (Fig. 12).

Over the 2021–2025 cohort, the proportion of NAS approvals with an orphan designation varied year-on-year but generally increased compared with 2016–2020. The largest increase was observed for Swissmedic (from 34% to 55%), followed by PMDA (from 32% to 39%), TGA (from 32% to 37%), FDA (from 51% to 56%) and EMA (from 37% to 40%).

The general increase in NAS approvals with orphan designation may reflect greater disease stratification and the expansion of company R&D pipelines alongside growing regulatory commitment to addressing unmet medical needs. The variation observed across authorities may also stem from differences in orphan designation criteria or the specific indication submitted by sponsors.

Figure 13. Trends in median approval time by orphan designation in NAS approvals across six regulatory authorities (2021–2025)



***Approval time** is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.*
**Health Canada does not currently have an orphan policy; this data shows the number of medicines that were approved by Health Canada that were classified as orphan by either FDA, EMA or TGA.*

Orphan-designated NAS approvals generally had shorter median approval times than non-orphan NAS approvals. In 2025, PMDA had the fastest median approval time for orphan products at 269 days, followed by FDA (322 days), TGA (373 days), EMA (452 days) and Swissmedic (452 days) (Fig. 13). The shorter timelines observed at PMDA likely reflect a higher proportion of expedited reviews to orphan-designated applications, as part of its broader efforts to address unmet medical needs.

In 2025, PMDA had shorter median approval times for orphan NASs than for non-orphan NASs (−70 days), whereas EMA (+6 days), TGA (+24 days), Swissmedic (+51 days), and FDA (+77 days) showed the opposite pattern. These differences likely reflect variation in pathway use and product mix rather than a direct effect of orphan designation.

Common approvals across the six regulatory authorities

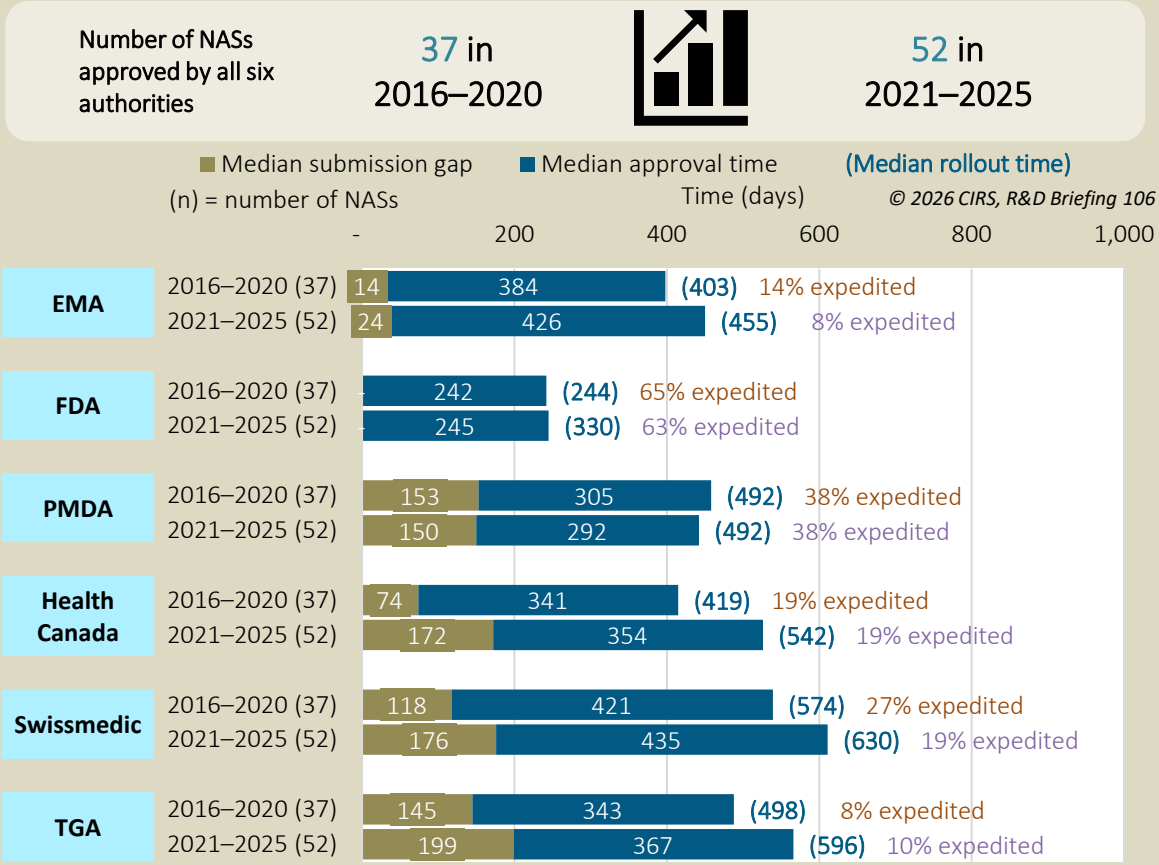
To benchmark regulatory performance accurately, it is important to focus on compounds approved by all six authorities. This assessment was conducted comparing two five-year approval cohorts (2016–2020 and 2021–2025) to identify trends.

The number of NASs approved by all six authorities increased from 37 in 2016–2020 to 52 in 2021–2025, Alongside the expansion in global approvals, submission sequencing has shifted. PMDA submissions are now occurring earlier relative to other agencies, as reflected by larger median submission gaps for Health Canada, Swissmedic and TGA.

The rollout time, consisting of the submission gap and approval time (Fig. 14), can be influenced by factors such as company strategy and the use of expedited pathways. The fastest overall median rollout time for the 2021–2025 cohort was observed for FDA (330 days), reflecting early submissions and shorter review times linked to the high use of expedited reviews (63% of approved NASs). This was followed by EMA (455 days), PMDA (492 days), Health Canada (542 days), TGA (596 days) and Swissmedic (630 days). Compared with 2016–2020, median rollout times for 2021–2025 remained unchanged at PMDA, while increases were observed at EMA (52 days), Swissmedic (56 days), FDA (86 days), TGA (98 days), and Health Canada (123 days).

For the 2021–2025 cohort, submission gaps varied across the agencies but increased for most compared with 2016–2020. Submissions to FDA and EMA remained closely aligned, with median gaps of 0 and 24 days, respectively. In contrast, the largest increase was observed for Health Canada (+98 days, from 74 to 172 days), followed by Swissmedic (+58 days, from 118 to 176 days) and TGA (+54 days, from 145 to 199 days), while PMDA showed a slight decrease (−3 days, from 153 to 150 days). As a result, submission timings to PMDA are becoming more aligned with Health Canada, Swissmedic and TGA.

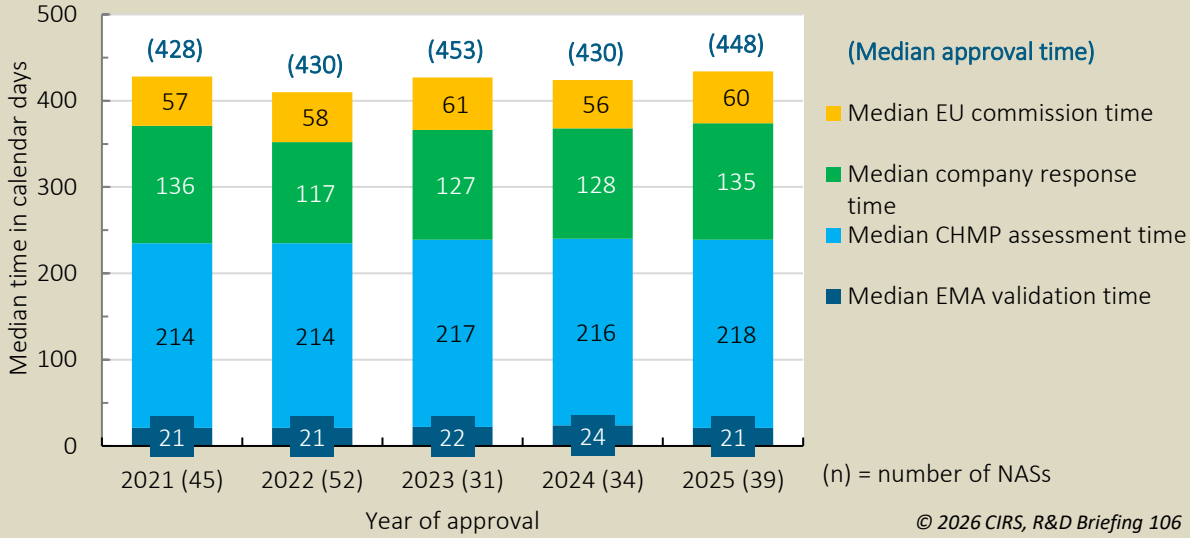
Figure 14. Median submission, approval, and rollout timelines and expedited review uptake for NASs approved by all six authorities (2016–2020 vs 2021–2025)



Submission gap *is calculated as the time from the date of submission at the first regulatory authority to the date of regulatory submission to the target agency.* ***Approval time*** *is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.* ***Rollout time*** *is calculated from the date of submission at the first regulatory authority to the date of regulatory approval at the target agency.* ***Expedited review*** *includes EMA's Accelerated Assessment; Priority Review for FDA, Health Canada, TGA, and PMDA (including all orphan NASs under PMDA); and Swissmedic's Fast-track and Temporary Authorisation procedures (excluding ex officio cases).*

Focus on the elements of EMA regulatory timelines

Figure 15. Median timelines for key intervals in the EU centralised marketing authorisation process for NASs by year of approval (2021–2025)



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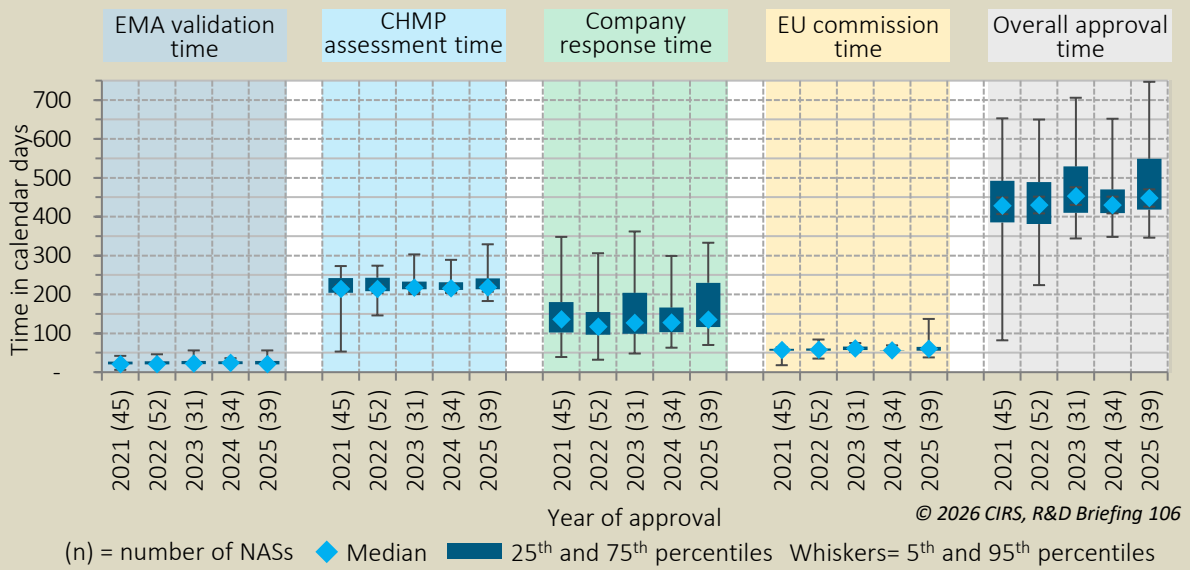
EMA approval timelines for NASs were analysed by breaking down the overall process into four key intervals: validation time, CHMP scientific assessment time, company response time, and European Commission time. Results show a high level of consistency in both median values and IQRs from 2021 to 2025, reflecting the structured and legislated timelines of the centralised procedure (Fig. 15 & 16).

Over the five years, EMA's median approval time remained consistent, ranging from 428 days in 2021 to 448 days in 2025. In 2025, validation time accounted for 5% of EMA's overall median approval time (21 days), CHMP assessment accounted for 49% (218 days), company response time accounted for 30% (135 days), and European Commission decision time accounted for 13% (60 days).

Note: Percentages are calculated using median durations for each interval independently; as a result, they do not sum up to 100%.

In 2025, EMA's overall approval time IQR was 131 days, the highest of the last five years, with company response time also reaching its highest IQR at 114 days. The IQR for CHMP assessment time was 28 days, followed by 10 days for European Commission decision time and 9 days for EMA validation time.

Figure 16. Variability in timelines for key intervals of the EU centralised marketing authorisation procedure (2021–2025)



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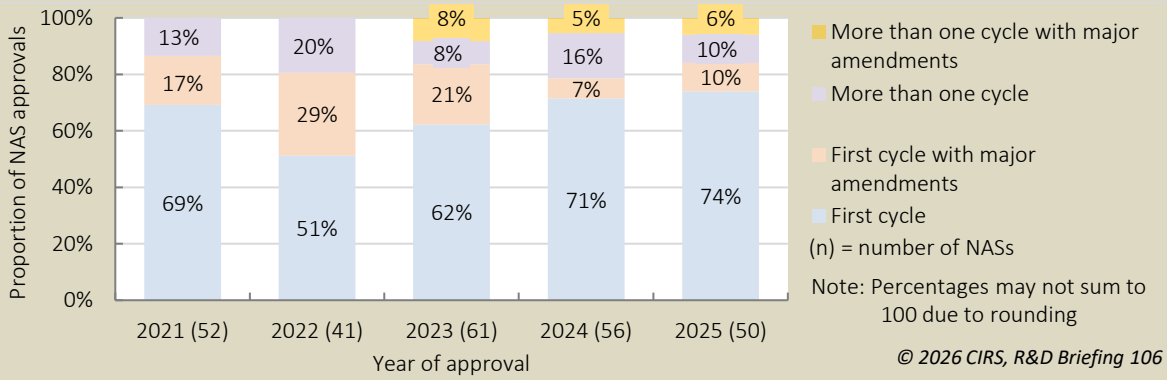
***EMA validation time** is calculated from the date the EMA receives the application to the date the procedure starts. **CHMP assessment time** is calculated from the date the procedure starts to the date the CHMP issues a positive opinion, excluding any clock stops. **Company response time** is calculated as the sum of periods from the date the CHMP adopts a consolidated List of Questions or List of Outstanding Issues to the date the applicant submits the corresponding responses. **EU Commission time** is calculated from the date the CHMP adopts its final opinion to the date the European Commission grants marketing authorisation. **Overall approval time** is calculated as the sum of these four periods.*

Focus on FDA's review cycles and major amendments involvement

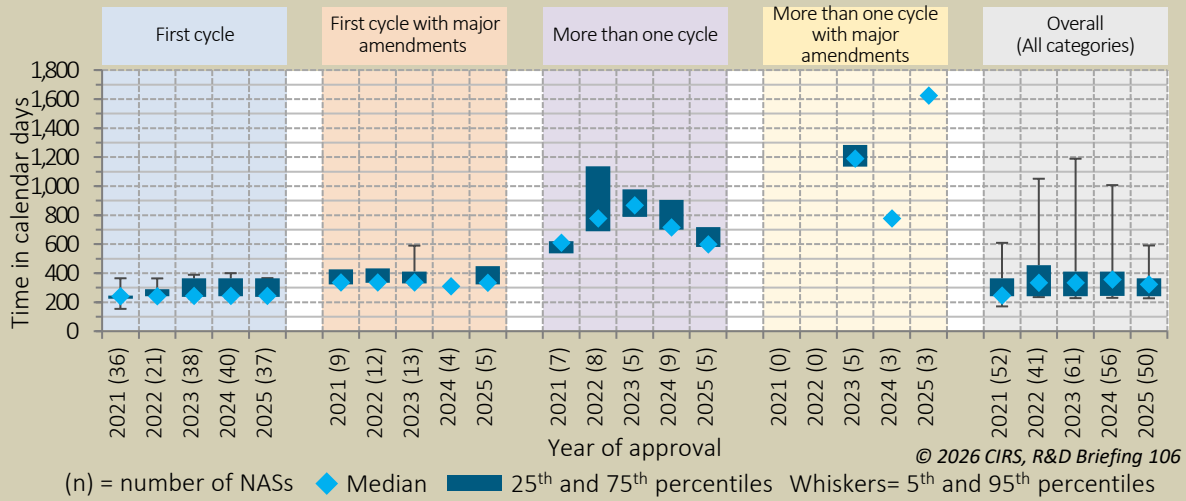
Figure 17. Distribution of FDA NAS approvals by review cycle and involvement of major amendments (2021–2025)



In 2025, 74% of NAS approvals at the FDA were granted within the first review cycle, the highest proportion observed over 2021-2025 (Fig. 17). The use of major amendments, which peaked in 2022, enables sponsors to address deficiencies within the ongoing review and avoid receiving a Complete Response Letter. This mechanism, in turn, appears to support the FDA in maintaining around 80% of NAS approvals within a single review cycle.

Notably, approvals following multiple cycles with major amendments were absent in 2021–2022 but emerged after 2023, accounting for 5%–8% of approvals, with 6% in 2025. This suggests that a small but persistent proportion of NASs have obtained approval only after following multiple cycles with major amendments over the last three years.

Figure 18. Variability in FDA NAS approval times across review cycles and major amendment involvement (2021–2025)



***Approval time** is calculated from the date of submission to the date of approval by the agency. Median is not shown when (n) is lower than three. The interquartile range (IQR) or the range between the 25th and 75th percentiles is shown when (n) is equal or greater than five. The range between the 5th and 95th percentiles is shown when (n) is equal or greater than ten.*

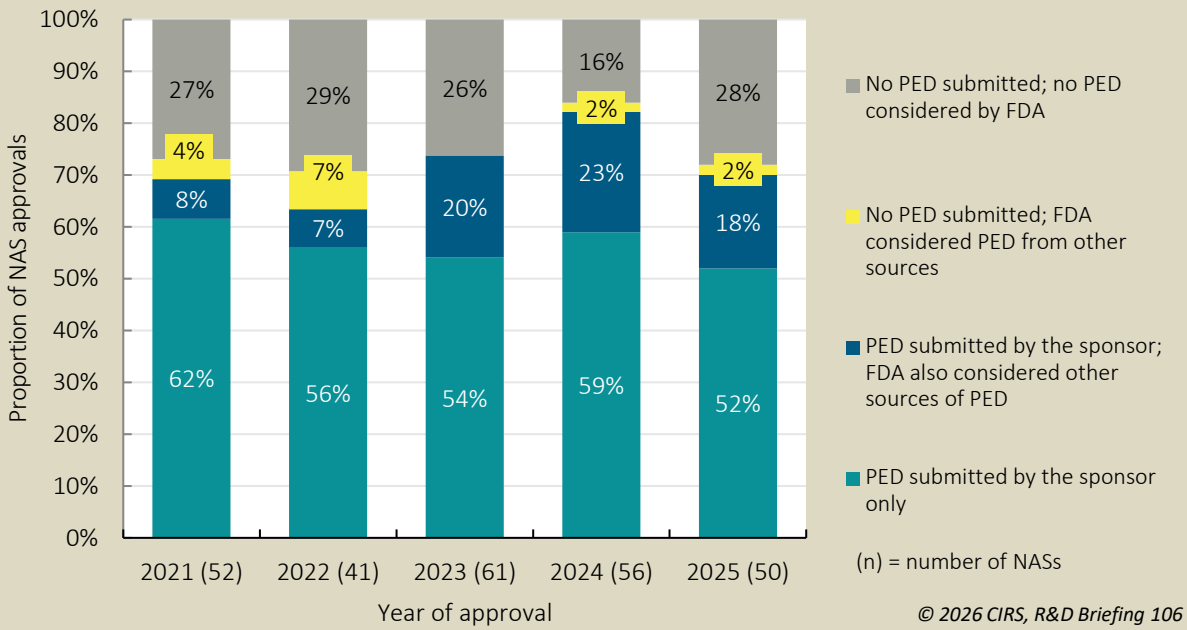
FDA approval times for NASs between 2021 and 2025 varied markedly based on the number of review cycles and the use of major amendments (Fig. 18). NASs approved in the first review cycle without major amendments had the shortest timelines, with a median approval time of 243 days in 2025. In terms of variability, IQRs were notably narrower for 2021 and 2022 compared to 2023-2025, ranging from 21 days in 2021 to 128 days in 2025. The narrowest IQR observed in 2021 coincides with one of the highest levels of Priority Review use, as shown in Figures 5 and 6, suggesting that increased use of expedited pathways led to a smaller range of timelines. In contrast, NASs approved after more than one cycle often exceeded 500 calendar days and exhibited wider IQRs, contributing most to the upper-range outliers in FDA approval time distributions.

Unresolved deficiencies during the first review led to Complete Response Letters, which frequently cited issues related to clinical evidence, product quality, statistical methodology, device usability, and facility inspections. Although fewer in number, these approvals highlight how submission quality, strategic planning, and early regulatory engagement can significantly influence approval time predictability.

Focus on FDA's inclusion and consideration of patient experience data (PED)

In recent years, FDA has intensified its efforts to incorporate patient experience data (PED) into regulatory decision making as part of its broader Patient-Focused Drug Development (PFDD) initiative. Tracking how frequently PED is submitted by sponsors or independently identified and considered by the authority provides insight into the practical uptake of these efforts. It is important to note, however, that the figures presented reflect only the inclusion or consideration of PED as documented in PED tables within multidisciplinary, integrated, or clinical reviews, and do not indicate the extent to which PED influenced the final approval decision. Figure 19 summarises the use of PED in FDA NAS approvals between 2021 and 2025.

Figure 19. Inclusion and consideration of patient experience data in FDA NAS approvals (2021–2025)



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While the overall inclusion of patient experience data (PED) in FDA NAS approvals decreased in 2025 to 72%, compared with 84% in 2024, levels remain broadly aligned with earlier years. The FDA's use of multiple sources of PED - alongside sponsor-submitted data - has increased from 12% in 2021 to 20% in 2025, pointing to a more proactive and diversified approach to integrating patient evidence (Fig. 19).

This overall decrease of applications that included/considered PED in 2025 was mainly driven by a decrease in applications where PED was *"submitted by the sponsor only",* from 59% in 2024 to 52% in 2025, and in applications where PED was "*submitted by the sponsor and FDA also considered other sources of PED"* from 23% in 2024 to 18% in 2025.

In contrast, the steady increase in the proportion of PED considered by the FDA was mainly driven by an increase in applications where PED was "submitted by the sponsor, and FDA also considered other sources of PED" from 8% in 2021 to 18% in 2025.

Overall, the high proportion of NASs that included or considered PED aligns with the FDA's PFDD initiatives and reflect a broader interest in incorporating patient perspectives into benefit–risk assessments. Nonetheless, the lack of publicly available details on how PED is weighed during regulatory reviews makes it difficult to assess its actual impact on decision-making, review timelines, and ultimately, on the availability of medicines.

Summary of NAS approvals in 2025 by the six authorities

This table summarises approval times for NASs approvals granted in 2025 by the six regulatory authorities, broken down by product type, review type and major therapeutic area.

Agency Median approval time in calendar days	EMA  p. 16	FDA  p. 17	PMDA  p. 18	Health Canada  p. 19	Swissmedic  p. 20	TGA  p. 21
Number of NAS approvals	39	50	40	44	34	42
NAS median overall approval time (days)	448	322	292	369	413	350
By biologics (days)	502	297	269	388	425	354
By chemicals (days)	446	326	298	352	401	349
By standard review (days)	452	365	339	389	448	352
By expedited review (days)	235	242	269	235	285	306
By orphans (days)	452	322	269	358*	452	373
By anticancer and immuno-modulators (days)	445	242	269	353	426	347

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Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time.
** Health Canada does not have an orphan policy; however, in 2025, Health Canada approved 29 NASs classified as orphan by either the FDA, EMA, or TGA, with a median approval time of 358 days.*

EMA APPROVED A TOTAL OF 39 NASs IN 2025, WITH A MEDIAN APPROVAL TIME OF 448 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 388 DAYS

THE MEDIAN EU COMMISSION TIME WAS 60 DAYS, THE EMA REVIEW TIME 250 DAYS AND THE COMPANY TIME 135 DAYS

Type of Medicine

17 BIOLOGIC NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 502 DAYS

22 CHEMICAL NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 446 DAYS

17 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 445 DAYS

22 NASs IN OTHER THERAPY AREAS APPRNASS IN 2025, WITH A MEDIAN APPROVAL TIME OF 458 DAYS

Designation and Review Type

2 EXPEDITED NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 235 DAYS; THIS IS 217 DAYS FASTER THAN THE MEDIAN OF THE 37 STANDARD NAS APPROVALS IN 2025

15 ORPHAN NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 452 DAYS; THIS IS 06 DAYS SLOWER THAN THE MEDIAN OF THE 24 NON-ORPHAN NAS APPROVALS IN 2025

Availability by EMA

21% OF THE NASs APPROVED BY EMA IN 2025 WERE EITHER FIRST APPROVED BY THE AGENCY OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY ANOTHER AGENCY

79% OF THE NASs APPROVED BY EMA IN 2025 HAD ALREADY BEEN APPROVED BY ANOTHER AGENCY MORE THAN ONE MONTH EARLIER

THE MEDIAN SUBMISSION GAP TO EMA FOR THESE NASs WAS 84 DAYS

Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. 'Expedited review' refers to EMA 'Accelerated Assessment. Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

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FDA (CDER AND CBER) APPROVED A TOTAL OF 50 NASs IN 2025, WITH A MEDIAN APPROVAL TIME OF 322 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 322 DAYS

84% OF THE NAS APPROVALS WERE GRANTED BY THE FDA IN THE FIRST SCIENTIFIC REVIEW CYCLE

Type of Medicine

16 BIOLOGIC NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 297 DAYS

34 CHEMICAL NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 326 DAYS

19 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 242 DAYS

31 NASS IN OTHER THERAPY AREAS APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 364 DAYS

Designation and Review Type

28 EXPEDITED NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 242 DAYS; THIS IS 123 DAYS FASTER THAN THE MEDIAN OF THE 22 STANDARD NAS APPROVALS IN 2025

27 ORPHAN NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 322 DAYS; THIS IS 77 DAYS SLOWER THAN THE MEDIAN OF THE 23 NON-ORPHAN NAS APPROVALS IN 2025

Availability by FDA

88% OF THE NASs APPROVED BY FDA IN 2025 WERE EITHER FIRST APPROVED BY THE AGENCY OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY ANOTHER AGENCY

12% OF THE NASs APPROVED BY FDA IN 2025 HAD ALREADY BEEN APPROVED BY ANOTHER AGENCY MORE THAN ONE MONTH EARLIER

THE MEDIAN SUBMISSION GAP TO FDA FOR THESE NASs WAS 62 DAYS

'Expedited review' refers to FDA 'Priority Review'. Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

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PMDA APPROVED A TOTAL OF 40 NASs IN 2025, WITH A MEDIAN APPROVAL TIME OF 292 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 271 DAYS

Type of Medicine

12 BIOLOGIC NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 269 DAYS

28 CHEMICAL NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 298 DAYS

15 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 269 DAYS

25 NASs IN OTHER THERAPY AREAS APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 297 DAYS

Designation and Review Type

21 EXPEDITED NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 269 DAYS; THIS IS 70 DAYS FASTER THAN THE MEDIAN OF THE 19 STANDARD NAS APPROVALS IN 2025

21 ORPHAN NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 269 DAYS; THIS IS 70 DAYS FASTER THAN THE MEDIAN OF THE 19 NON-ORPHAN NAS APPROVALS IN 2025

Availability by PMDA

13% OF THE NASs APPROVED BY PMDA IN 2025 WERE EITHER FIRST APPROVED BY THE AGENCY OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY ANOTHER AGENCY

88% OF THE NASs APPROVED BY PMDA IN 2025 HAD ALREADY BEEN APPROVED BY ANOTHER AGENCY MORE THAN ONE MONTH EARLIER

THE MEDIAN SUBMISSION GAP TO PMDA FOR THESE NASs WAS 989 DAYS

'Expedited review' refers to PMDA 'Priority Review'. Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

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Focus: NAS approvals at Health Canada in 2025 R&D Briefing 106

HEALTH CANADA APPROVED A TOTAL OF 44 NASs IN 2025, WITH A MEDIAN APPROVAL TIME OF 369 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 369 DAYS

Type of Medicine

19 BIOLOGIC NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 388 DAYS

25 CHEMICAL NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 352 DAYS

17 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 353 DAYS

27 NASs IN OTHER THERAPY AREAS APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 411 DAYS

Designation and Review Type

11 EXPEDITED NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 235 DAYS; THIS IS 154 DAYS FASTER THAN THE MEDIAN OF THE 33 STANDARD NAS APPROVALS IN 2025

HEALTH CANADA DOES NOT HAVE AN ORPHAN POLICY; HOWEVER, 29 NASS THAT WERE CLASSIFIED AS ORPHAN BY EITHER FDA, EMA OR TGA WERE APPROVED BY HEALTH CANADA IN 2025, WITH A MEDIAN APPROVAL TIME OF 358 DAYS

Availability by Health Canada

2% OF THE NASs APPROVED BY HEALTH CANADA IN 2025 WERE EITHER FIRST APPROVED BY THE AGENCY OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY ANOTHER AGENCY

98% OF THE NASs APPROVED BY HEALTH CANADA IN 2025 HAD ALREADY BEEN APPROVED BY ANOTHER AGENCY MORE THAN ONE MONTH EARLIER

THE MEDIAN SUBMISSION GAP TO HEALTH CANADA FOR THESE NASs WAS 674 DAYS

'Expedited review' refers to Health Canada's 'Priority Review'. Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

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SWISSMEDIC APPROVED A TOTAL OF 34 NASs IN 2025, WITH A MEDIAN APPROVAL TIME OF 413 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 303 DAYS

Type of Medicine

15 BIOLOGIC NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 425 DAYS

19 CHEMICAL NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 401 DAYS

16 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 426 DAYS

18 NASs IN OTHER THERAPY AREAS APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 397 DAYS

Designation and Review Type

6 EXPEDITED NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 285 DAYS; THIS IS 163 DAYS FASTER THAN THE MEDIAN OF THE 28 STANDARD NAS APPROVALS IN 2025

21 ORPHAN NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 452 DAYS; THIS IS 51 DAYS SLOWER THAN THE MEDIAN OF THE 13 NON-ORPHAN NAS APPROVALS IN 2025

Availability by Swissmedic

6% OF THE NASs APPROVED BY SWISSMEDIC IN 2025 WERE EITHER FIRST APPROVED BY THE AGENCY OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY ANOTHER AGENCY

94% OF THE NASs APPROVED BY SWISSMEDIC IN 2025 HAD ALREADY BEEN APPROVED BY ANOTHER AGENCY MORE THAN ONE MONTH EARLIER

THE MEDIAN SUBMISSION GAP TO SWISSMEDIC FOR THESE NASs WAS 618 DAYS

For Swissmedic, expedited reviews include 'Fast-track procedure' and 'Temporary Authorisation procedure'. For the purposes of this analysis, ex officio temporary authorisations were considered to have been reviewed under the standard procedure.

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TGA APPROVED A TOTAL OF 42 NASs IN 2025, WITH A MEDIAN APPROVAL TIME OF 350 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 350 DAYS

Type of Medicine

23 BIOLOGIC NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 354 DAYS

19 CHEMICAL NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 349 DAYS

16 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 347 DAYS

26 NASs IN OTHER THERAPY AREAS APPROVED IN 2025, WITH A MEDIAN APPROVAL TIME OF 352 DAYS

Designation and Review Type

4 EXPEDITED NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 306 DAYS; THIS IS 46 DAYS FASTER THAN THE MEDIAN OF THE 38 STANDARD NAS APPROVALS IN 2025

15 ORPHAN NAS APPROVALS IN 2025, WITH A MEDIAN APPROVAL TIME OF 373 DAYS; THIS IS 24 DAYS SLOWER THAN THE MEDIAN OF THE 27 NON-ORPHAN NAS APPROVALS IN 2025

Availability by TGA

7% OF THE NASs APPROVED BY TGA IN 2025 WERE EITHER FIRST APPROVED BY THE AGENCY OR WITHIN ONE MONTH OF THEIR FIRST APPROVAL BY ANOTHER AGENCY

93% OF THE NASs APPROVED BY TGA IN 2025 HAD ALREADY BEEN APPROVED BY ANOTHER AGENCY MORE THAN ONE MONTH EARLIER

THE MEDIAN SUBMISSION GAP TO TGA FOR THESE NASs WAS 802 DAYS

'Expedited review' refers to the 'Priority Review' of TGA introduced in 2017. Submission gap is the date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

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Definitions: Facilitated regulatory pathways

	What is it?	Advantage
FDA Priority Review	A process that directs resources to the evaluation of drugs that represent significant improvements in safety or effectiveness compared with standard applications	• Review time shortened from 10 to 6 months
FDA Accelerated Approval	Regulation allowing drugs for serious conditions that fulfil an unmet medical need to be approved based on a surrogate endpoint	• Conditional approval granted using surrogate endpoint(s) from phase 2 trials or interim phase 3 data; confirmatory trials with hard clinical endpoints required
FDA Fast Track	A process designed to facilitate the development and expedite the review of drugs to treat serious conditions and fulfil an unmet medical need	• More frequent meetings with FDA to discuss drug development plan • More frequent communication on clinical trials design • Option for rolling data submission
FDA Breakthrough Therapy	A process designed to expedite the development and review of drugs that may demonstrate substantial improvement over available therapy	• All Fast Track designation features • Intensive guidance on an efficient drug development program from phase 1 • Organisational commitment with senior managers • Option for priority review
Real-Time Oncology Review (RTOR)	A programme launched by the FDA Oncology Center of Excellence (OCE), it allows FDA to access and review key data ahead of time, prior to official submission	• RTOR allows the FDA to review much of the data earlier, before the applicant formally submits the complete application.
EMA Accelerated Assessment	A process designed to expedite products of major interest in terms of public health and therapeutic innovation	• Committee for Medicinal Products for Human Use (CHMP) opinion shortened from 210 days to 150 days
EMA Conditional Approval	Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved with limited clinical safety or efficacy data, provided a positive benefit-risk balance	• Conditional approval is granted before all data are available (valid for one year, on a renewable basis; once pending studies are provided, it can become a “normal” marketing authorisation)
EMA Exceptional Circum-stances	Regulation allowing drugs fulfilling unmet medical need for severe, life-threatening or rare diseases to be approved without comprehensive efficacy and safety data	• Conditional approval is granted before all data are available (reviewed annually to re-assess the risk-benefit balance)
EMA PRIME (Priority Medicines)	A scheme to enhance support for the development of medicines that target an unmet medical need. It is based on enhanced interaction and early dialogue with developers of promising medicines, to optimise development and speed evaluation.	• Early dialogue with EMA (appointed rapporteur) • Provision of scientific advice, involving additional stakeholders (e.g. HTA) • Dedicated point of contact from EMA • Option of Accelerated Assessment
PMDA Priority Review	A process that provides faster access to new therapies responding to high medical needs; includes products such as orphans, HIV medicines	• Review time shortened from 9 to 6 months
PMDA Conditional Early Approval	A system to put highly useful and effective drugs for treating serious diseases into practical use as early as possible	• Early application through confirmation of a certain degree of efficacy and safety • Shorten overall review times for priority review products
PMDA Sakigake (pioneer)	A system to put highly useful and effective drugs for treating serious diseases into practical use as early as possible	• All Priority Review designation features • Prioritised clinical trial and pre-application consultation • Assigned PMDA manager as a concierge • Post-marketing safety measures

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Definitions: Facilitated regulatory pathways *(cont.)*

	What is it?	Advantage
Health Canada Priority	A fast-track status for medicines for severe, debilitating or life-threatening disease; to address unmet medical need and where a high therapeutic benefit can be expected	• Review time shortened from 300 to 180 days
Health Canada Conditional (NOC/c)	Authorisation to market a new promising drug with the condition that the sponsor undertakes additional studies to verify the clinical benefit	• Earlier marketing of promising drugs for serious conditions before the drugs have definitively demonstrated clinical efficacy
Swissmedic Fast-Track (Art. 7 TPO)	A rapid review of applications for severe, debilitating or life-threatening disease; to address unmet medical need and where a high therapeutic benefit can be expected	• Review time shortened from 330 to 140 days
Temporary authorisation (Art. 9a TPA)	Temporary and conditioned authorisation of medicinal products for life-threatening or debilitating diseases, if they are compatible with health protection, a major therapeutic benefit can be expected, and no therapeutic alternative is available in Switzerland.	• Review time shortened from 330 to 140 days • A temporary authorisation granted for a maximum of two years
Swissmedic Prior Notification	A process to enable applicants to notify their submission date at an early stage, so that Swissmedic can draw up a streamlined and precise schedule for the review	• 20% faster processing time and fixed planning offered by this procedure are subject to a fee surcharge of 100%
Art.13 TPA	A process to authorise medicinal products that have already been approved in a country with a comparable medicinal product control system, taking account of the results of the trials conducted for this purpose provided that some requirements are satisfied	• In justified cases Swissmedic may reduce the scale of scientific assessments, either on request or ex officio, based on the result of the corresponding assessment by the foreign authority (e.g. USA FDA or EMA)
Art.14 TPA	An authorisation procedure for medicinal products with active substances that has been authorised in an EU or EFTA country for at least 10 years	• A simplified procedure where a review of original clinical documentation is generally only admissible for bioequivalence studies, e.g. where the pharmaceutical forms differ
TGA Priority	A formal mechanism for faster assessment of vital and life-saving medicines for severe, debilitating or life-threatening disease, to address unmet medical need and where a high therapeutic benefit can be expected	• Review time shortened from 220 to 150 working days • Dynamic process with rolling questions and more flexible arrangements for accessing advice
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	• Conditional approval is granted based on preliminary clinical data (valid for a maximum of 6 years)
Comparable overseas regulators (CORs)	The TGA makes use of assessments from comparable overseas regulators (CORs), where possible, in the regulation of prescription medicines.	Shortened evaluation and decision timeframe for prescription medicines that have already been approved by a COR partner: • For COR-A the timeframe is 120 working days • For COR-B the timeframe is 175 working days
Access Consortium	Medium-sized coalition to promote greater regulatory collaboration and alignment of regulatory requirements between Australia-Canada-Singapore-Switzerland-UK	• Maximises international cooperation, reduces duplication, and increases each agency's capacity to ensure consumers have timely access to high quality, safe and effective therapeutic products. • Maximises the use of up-to-date technical expertise, and ensures a consistent, contemporary approach to assessing the benefits and risks associated with the use of therapeutic products
Project Orbis	An initiative of the FDA Oncology Center of Excellence (OCE), provides a framework for concurrent submission and review of oncology products among international partners –Australia-Brazil-Canada-Singapore-Switzerland-UK-US	

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Approval time
Time calculated from the date of submission to the date of approval by the agency. This time includes agency and company time.

Biological/Biotechnology product
A substance isolated from animal tissues or product produced by recombinant DNA or hybridoma technology and expressed in cell lines, transgenic animals or transgenic plants for therapeutic, prophylactic or in vivo diagnostic use in humans.

Chemical entity
An entity produced by chemical synthesis.

EMA Company response time
Time calculated as the sum of periods between the date the CHMP agrees on the consolidated List of Questions/ List of Outstanding Issues to be sent to the applicant and the date in which the applicant submits the responses.

EMA review time
Time calculated as the difference among the approval time minus the sum of the company time and the EU commission time.

EU commission time
Time calculated from the date of end of scientific assessment to the date of approval by the EU commission.

Expedited review
Refers to EMA 'Accelerated Assessment', FDA/PMDA/Health Canada/TGA 'Priority Review' and Swissmedic 'Fast-track' and Temporary Authorisation procedures (excluding ex officio cases).

Facilitated regulatory pathway
Regulatory pathway designed to facilitate availability, accelerate review and/or approval of medicines where there is an unmet medical need by providing alternatives to standard regulatory review routes.

Interquartile range (IQR)
The interquartile range is calculated as the difference between the 75th percentile and the 25th percentile of a distribution of measurements.

New active substances (NASs)*
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 through changes to the 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.

Applications that are excluded from the study:

- Vaccines
- Biosimilars
- 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).
- Emergency use or Special authorisations derived from an emergency (e.g. COVID-19 pandemic)
- Non-modified autologous cell therapies

*The full list of NASs approved by each jurisdiction in 2025 will be available on the CIRS website.

Real-world data (FDA definition)
Real-world data are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWD can come from a number of sources, for example:

- Electronic health records.
- Claims and billing activities.
- Product and disease registries.
- Patient-generated data including in home-use settings.
- Data gathered from other sources that can inform on health status, such as mobile devices.

Review cycle
A bounded regulatory evaluation period during which a health authority assesses a submitted dossier (or a resubmitted version), against defined standards of quality, safety, and efficacy, culminating in a formal regulatory outcome (e.g., approval, refusal, or request for additional information).

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Rollout time
Time calculated from date of submission at the first regulatory agency to the date of regulatory approval at the target agency.

Submission gap
Time calculated from date of submission at the first regulatory agency to the date of regulatory submission to the target agency.

Time from submission to the end of scientific assessment
Time from submission to the end of scientific assessment has been defined as follows for the six agencies. It includes agency and company time and is calculated as time from acceptance of the submission for evaluation submission until:

- EMA: The CHMP issues an opinion for granting a marketing authorisation. Excluded is the time from CHMP opinion to final decision by the European Commission.
- FDA: The FDA action letter to approve is signed (FDA action date). This is equivalent to the regulatory approval, and therefore for FDA, time from acceptance of submission to end scientific assessment and time from acceptance of submission to approval are the same.
- PMDA: The First/Second Committee on New Drugs' meeting, when it is concluded that a marketing authorisation can be granted. Excluded is the time from New Drugs meeting to MHLW final decision.
- Health Canada: The last review stream is completed and the outcome letter is sent. Excluded is further time to ensure the information on file is complete and properly filed, generate drug identification numbers, prepare an executive summary and prepare the Notice of Compliance (NOC) package for routing and sign off as well as time to check that requirements are met with respect to the Patented Medicines (NOC) Regulations and the data protection provisions .
- Swissmedic: The advisory committee review and decision is made and the outcome letter (preliminary decision) is sent. Excluded is the negotiation time with the sponsor regarding the label following the end of the scientific review.
- TGA: The delegate decision is made and the decision (outcome letter) is sent to the sponsor. This is equivalent to the regulatory approval, and therefore for TGA, time from acceptance of submission to end scientific assessment and time from acceptance of submission to approval are the same.

Top company
Pharmaceutical company with R&D spending ≥3 billion USD in 2024. Company R&D spending data was obtained from the Pharm Exec Top 50 Companies (2025) available at https://www.pharmexec.com/view/2025-pharm-exec-top-50-companies

World Health Organisation (WHO) ATC classification
- A - Alimentary and metabolism: Drugs for acid related disorders, gastrointestinal disorders, antiemetics and antinauseants, bile and liver therapy, laxatives, antidiarrheals, intestinal anti-inflammatory/anti-infective agents, drugs used in diabetes.
- B – Blood and blood forming organs: antithrombotic agents, antihemorrhagics, antianemic preparations, blood substitutes and perfusion solutions, other hematological agents.
- J - Anti-infectives: Antibacterials for systemic use, antimycotics for systemic use, antimycobacterials, antivirals for systemic use, immune sera and immunoglobulins, vaccines.
- L - Anticancer and immunomodulators: Antineoplastic agents, endocrine therapy, immunostimulants, immunosuppressive agents.
- N - Nervous system: Anesthetics, analgesics, antiepileptics, anti-parkinson drugs, psycholeptics, psychoanaleptics, other nervous system.

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The Centre for Innovation in Regulatory Science (CIRS) is a neutral, independent UK-based subsidiary of Clarivate plc. Its mission is to identify and apply 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 bodies 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, and grants.

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