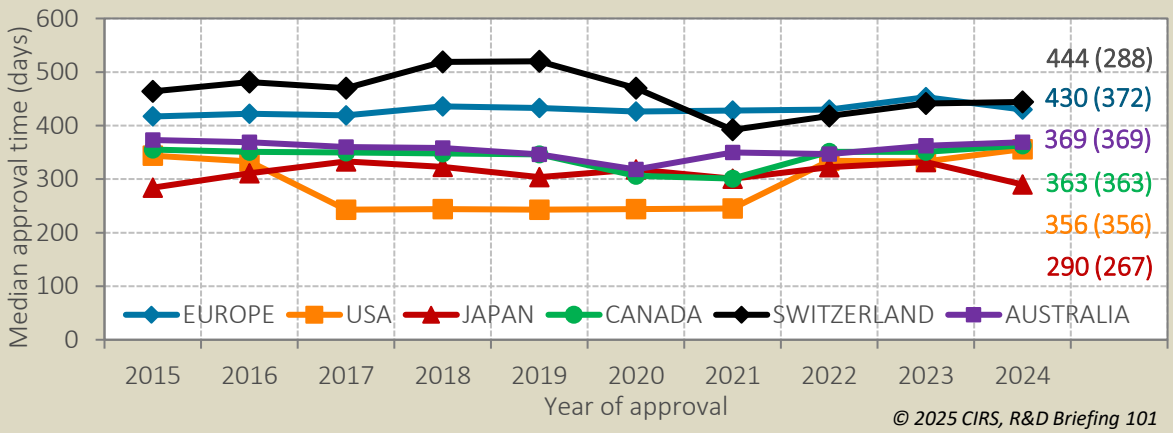
New drug approvals by six major authorities 2015-2024:

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 2024, while also retrospectively examining trends from 2015 to 2024. 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. The use of facilitated regulatory pathways (FRPs) is a major element of the submission and approval strategy and is a focus of this year's R&D Briefing.

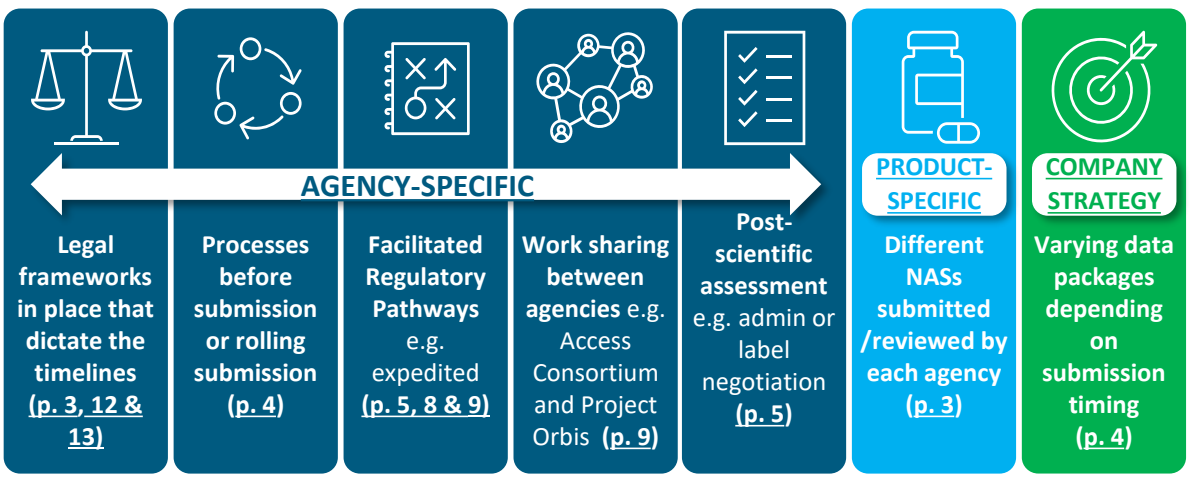
Contents

Median approval timelines for new active substances across six regulatory authorities (2015–2024)



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 2024; (N2) = median time from submission to the end of scientific assessment (see p. 25) for products approved in 2024.

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 is explored further in the infographic below and on the linked pages.



Key messages

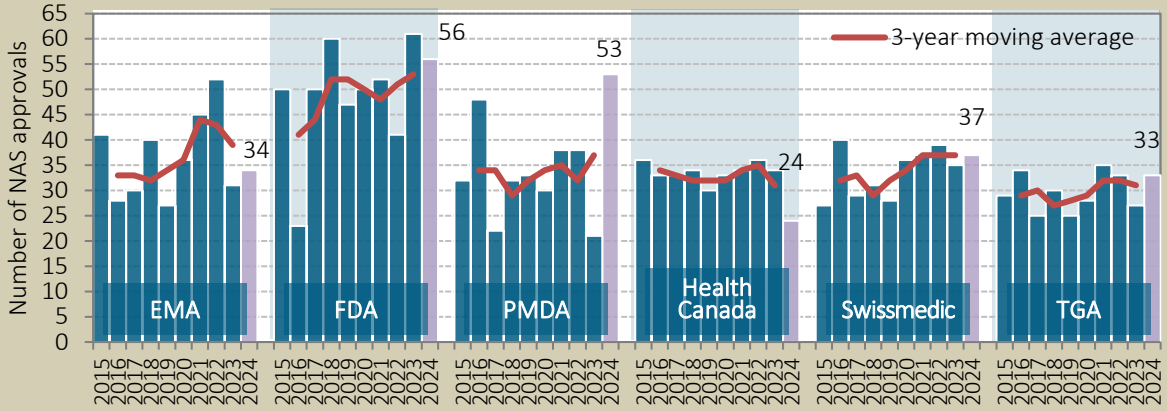
- Despite improvements over the past 20 years, NAS median approval times still vary across the six authorities. In 2024, the greatest difference in median approval times was 154 days between PMDA and Swissmedic. This difference was smaller when comparing the time from submission to the end of scientific assessment (see definition on p. 25).
- In 2024, FDA granted the highest number of NAS approvals (56), followed by PMDA (53), Swissmedic (37), EMA (34), TGA (33), and Health Canada (24) (Fig. 1). While FDA approved more products than its peers over the past decade, not all of them are internationalised promptly (see p. 4).
- In 2024, PMDA had the shortest median approval time (290 days), followed by FDA (356 days), then Health Canada (363), TGA (369), EMA (430) and Swissmedic (444) (Fig. 2).
- In 2024, FDA had the shortest median submission gap (0 days), indicating that at least half of the NASs were submitted to FDA first. This was followed by EMA (49 days), TGA (219 days), Health Canada (262 days), Swissmedic (417 days), and PMDA (727 days) (Fig. 3).
- In 2024, companies outside the Top 20 in R&D had longer median submission gaps than those within the Top 20 across all authorities except the FDA. The largest difference was observed for Swissmedic (553 days), followed by PMDA (430 days), Health Canada (329 days), TGA (311 days), and EMA (136 days) (Fig. 4).
- In 2024, the use of expedited review pathways for NAS approvals varied across agencies. FDA had the highest proportion (59%), followed by PMDA (34%), Health Canada (29%), Swissmedic (22%), and TGA (9%). EMA approved no NASs via accelerated assessment (0%) due to either withdrawn requests or reversions to standard review (Fig. 5).
- In 2024, expedited reviews had shorter median approval times than standard reviews across all six authorities. Health Canada had the shortest median for expedited reviews (223 days), while TGA had the longest (251 days). Swissmedic showed the largest difference between review types in 2024, with expedited approvals being 210 days faster than standard ones (Fig. 6).
- Between 2020 and 2024, anti-infective therapies had the shortest median approval time (284 days) among the six authorities. This was followed by alimentary and metabolism therapies (310 days), anti-cancer and immunomodulators (349 days), blood and blood forming organs (362 days), and nervous system (380 days) (Figs. 7 and 8).
- Of the top five therapeutic areas, anti-cancer and immunomodulatory therapies consistently accounted for the largest proportion of NAS approvals across all six regulatory authorities during the last decade, increasing from 47% in 2015–2019 to 57% in 2020–2024, while the other four areas remained stable or declined (Fig. 9).
- The use of expedited review pathways for alimentary and metabolism NAS approvals increased from 24% to 45%, and for blood and blood forming organs therapies from 26% to 36%, suggesting a shift in regulatory focus toward addressing emerging unmet medical needs (Fig.10).
- The use of facilitated regulatory pathways (FRPs, see p. 22 for definitions) increased for most authorities between 2020–2024 compared to 2015–2019. FDA was the authority that most frequently used FRPs between 2020–2024, with 75% of NAS approvals involving at least one FRP, followed by Swissmedic (66%), TGA (63%), Health Canada (53%), PMDA and EMA (37% each) (Fig. 11).
- In 2024, the proportion of NAS approvals granted by conditional, temporary, provisional pathways was 18% for both EMA and FDA, 14% for Swissmedic, 12% for TGA and 8% for Health Canada (Fig. 12).
- In 2024, the proportion of NAS approvals with an orphan designation was high across all authorities. For Swissmedic this was 65%, FDA 59%, EMA 47%, TGA 33%, and PMDA 32% (Fig. 14). Orphan NASs generally had shorter median approval times compared to non-orphans. PMDA had the fastest median approval time for orphans in 2024 (245 days), followed by FDA (275 days), TGA (321 days), Swissmedic (369 days), and EMA (418 days) (Fig. 15).
- The number of NASs approved by all six authorities increased from 42 to 44 between 2015–2019 and 2020–2024, suggesting stabilisation in global rollout. Compared with 2015–2019, rollout times decreased in 2020–2024 at PMDA (by 67 days), while increases were observed at Swissmedic (34 days), EMA (58 days), FDA (88 days), TGA (93 days), and Health Canada (138 days) (Fig. 16).
- From 2020 to 2024, EMA median approval times for NASs remained consistent, ranging from 426 to 453 days. In 2024, the median CHMP assessment accounted for 51% of the overall median, followed by company response (30%), European Commission decision (13%), and validation (6%) (Figs. 17 and 18).
- Although the proportion of first-cycle NAS approvals at the FDA declined to a low of 51% in 2022, it has since recovered, rising to 62% in 2023 and 71% in 2024. First-cycle approvals without major amendments had the shortest and most consistent approval timelines, while multi-cycle approvals with major amendments often exceeded 500 days (Figs. 19 and 20).
- The proportion of NAS approvals by FDA involving patient experience data (PED) increased from 58% in 2020 to 84% in 2024, driven mainly by sponsor-submitted and FDA-identified PED. Nonetheless, the lack of publicly available detail on how PED is weighted during regulatory reviews makes it difficult to assess its impact on decisions and timelines (Fig. 21).

See agency-specific infographics for 2024 snapshots:

EMA	FDA	PMDA	Health Canada	Swissmedic	TGA
p. 16	p. 17	p. 18	p. 19	p. 20	p. 21

Overall approvals

Figure 1. Trends in NAS approvals across six regulatory authorities (2015–2024)

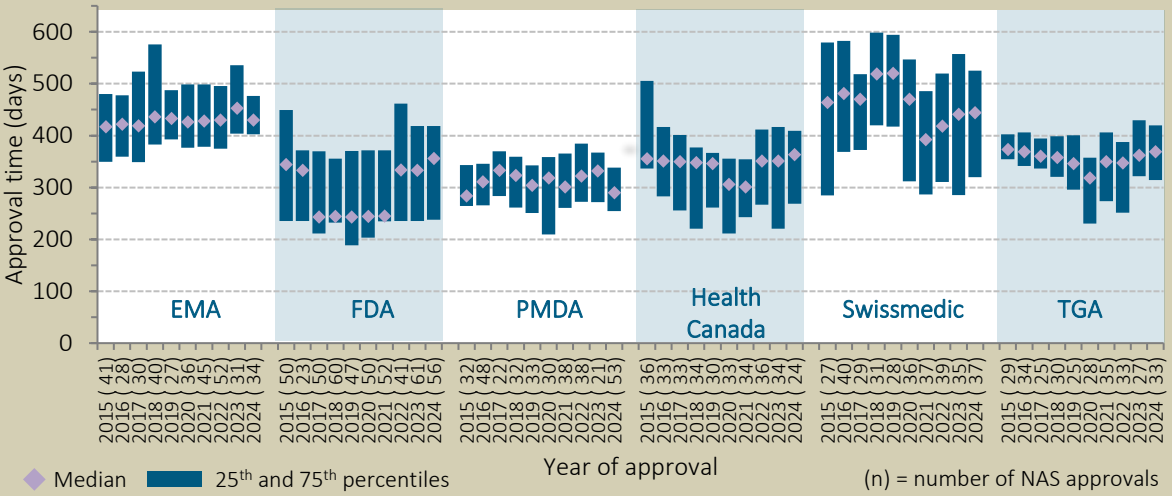


In 2024, FDA approved the highest number of NASs, with 56 approvals, followed by PMDA (53), Swissmedic (37), EMA (34), TGA (33) and Health Canada (24) (Fig. 1). While FDA consistently approved more NASs than its peers over the past decade, not all of these products are internationalised promptly, and some take considerable time to reach other markets (see p. 4).

Comparing the first and second halves of the decade (2015–2019 vs 2020–2024), the largest relative increases in NAS approvals were observed at EMA and Swissmedic (both 19%), followed by the FDA (13%), TGA (9%), and PMDA (8%). PMDA's sharp increase in 2024 reflects its batch-based approval approach and the influence of the Japanese fiscal year, which often results in approvals being concentrated in specific cycles.

The 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 (2015–2024)



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.

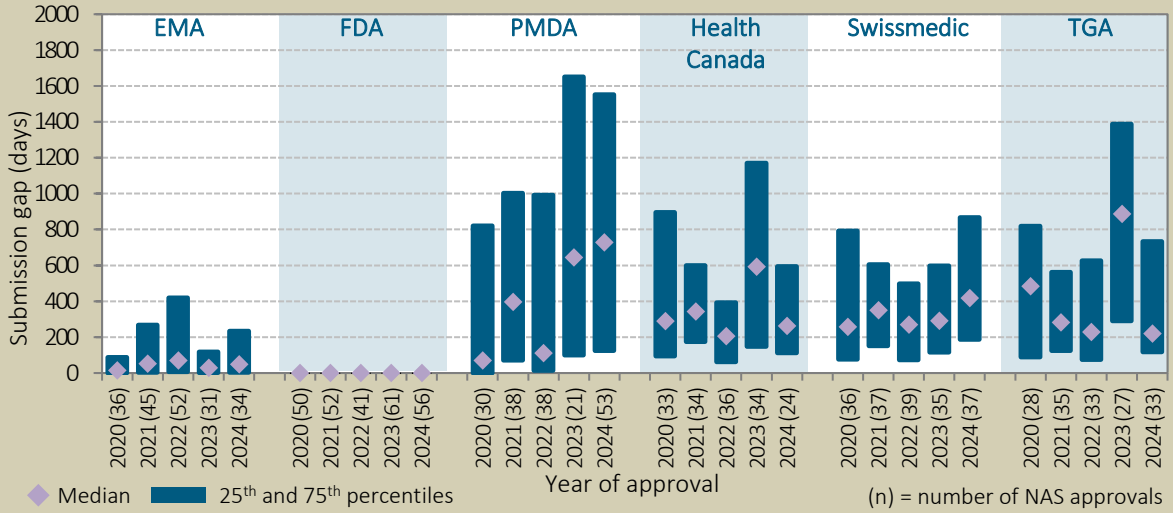
In 2024, the shortest median approval time was observed for PMDA, at 290 days (interquartile range [IQR] 71 days). Swissmedic had the longest median at 444 days (IQR 193), resulting in a 154-day difference between the two authorities. The FDA followed PMDA with 356 days (IQR 168), then Health Canada (363; IQR 128), TGA (369; IQR 92), and EMA (430; IQR 61) (Fig. 2).

While overall approval times varied across authorities, the difference was less pronounced when comparing the median time from submission to the end of scientific assessment. In fact, there was only a 21-day gap between PMDA and Swissmedic when approval times were calculated this way (see p. 1; definitions on p. 25).

Between 2021 and 2024, median approval times for both FDA and Health Canada increased by 111 days and 62 days, respectively.

Submission gap

Figure 3. Submission gap variability for NAS approvals across six regulatory authorities (2020–2024)



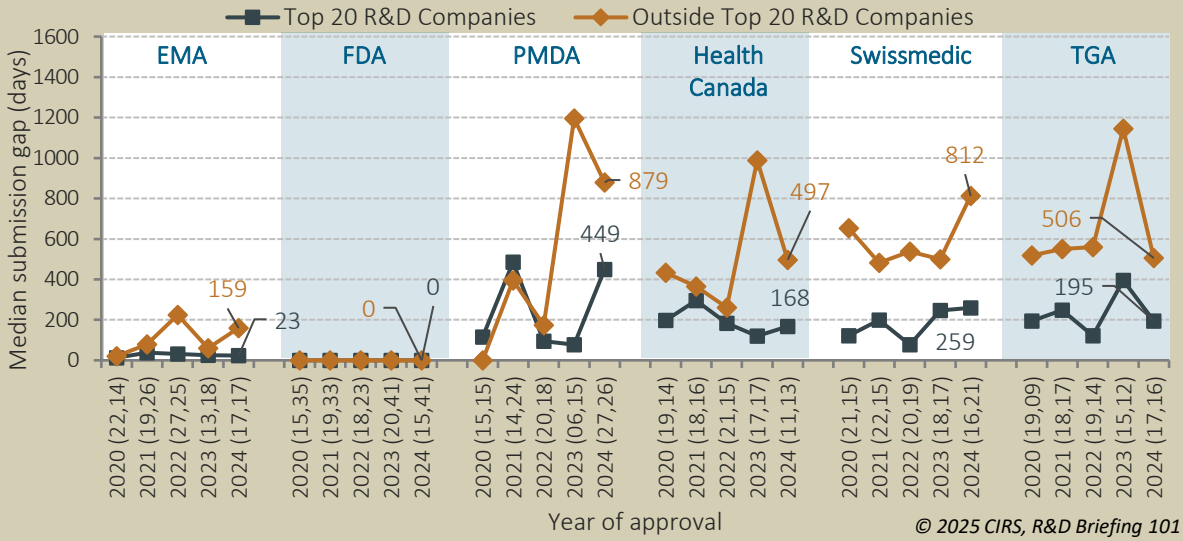
Submission gap is calculated as the time from the date of submission at the first regulatory authority to the date of regulatory submission to the target regulatory authority.

In 2024, FDA had the shortest median submission gap at 0 days, followed by EMA (49 days), TGA (219 days), Health Canada (262 days), Swissmedic (417 days), and PMDA (727 days). Submission gap variability also differed markedly across authorities, with IQRs ranging from 0 days (FDA) to 1,427 days (PMDA). EMA had the second-narrowest IQR at 229 days (Fig. 3).

In 2024, median submission gaps for TGA and Health Canada were similar to those observed between 2020 and 2022, suggesting that 2023 was an outlier year for these authorities. In terms of variability, IQRs for EMA, PMDA, Health Canada, and TGA also moved closer to their earlier-year baselines. In contrast, Swissmedic showed a wider spread in submission timing.

These shifts could indicate evolving company strategies, such as the increasing use of collaborative and work-sharing pathways in some regions, while others may be influenced by company size, where submissions from small companies often correlate with longer submission gaps.

Figure 4. Trends in submission gap by company size in NAS approvals across six regulatory authorities (2020–2024)



***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 20 R&D companies** were defined as pharmaceutical companies with R&D expenditures ≥ 3 billion USD in 2023, as reported in Pharm Exec Top 50 Companies (2024). **(n1,n2)** = (number of NAS approvals granted to Top 20 R&D companies, number of NAS approvals granted to Outside Top 20 R&D companies).*

Median submission gaps were longer for companies outside the Top 20 R&D companies compared to those within the Top 20. In 2024, the largest median difference between these two groups was seen for Swissmedic (553 days), followed by PMDA (430 days), Health Canada (329 days), TGA (311 days) and EMA (136 days) (Fig. 4).

These findings suggest that differences in companies' size and resources may impact their ability to engage in early and coordinated submissions, even when developing promising therapies.

Expedited review pathways

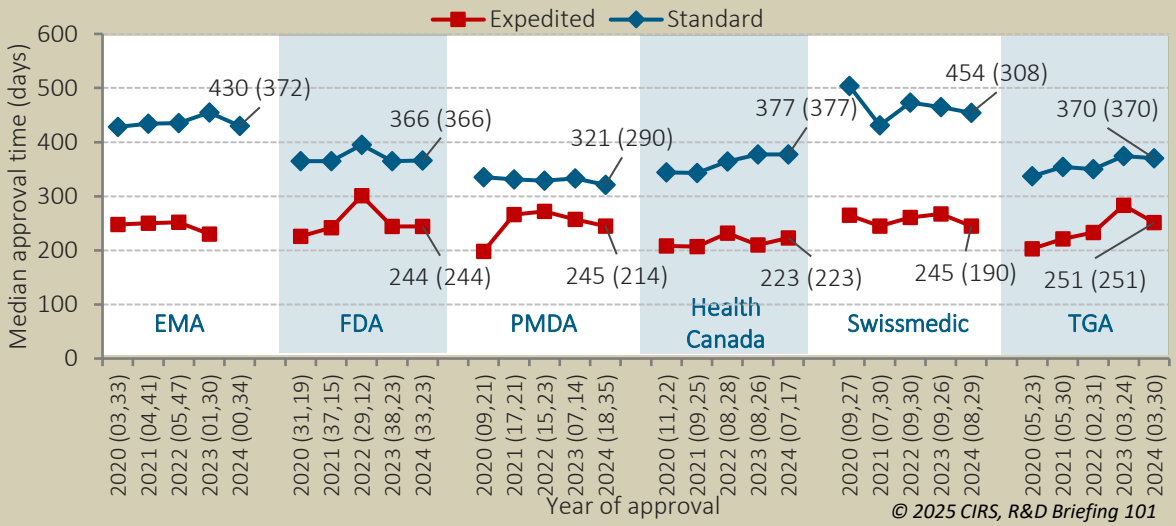
Figure 5. Use of expedited review pathways in NAS approvals across six regulatory authorities (2020–2024)

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 2024. FDA had the highest proportion at 59%, followed by PMDA (34%), Health Canada (29%), Swissmedic (22%), TGA (9%), while EMA had no NAS approvals via accelerated assessment during 2024 (0%) (Fig. 5). The overall rate of expedited approvals remained similar to 2023 outcomes across the six authorities.

Although EMA did not approve any NAS through an accelerated assessment in 2024, four applicants requested an expedited review. One withdrew their request, two were not granted due to not being considered of major public health interest, and one was reverted to standard review after clinical major objections and additional data submissions compromised the feasibility of maintaining an accelerated timeline.

Figure 6. Trends in median approval time by review type in NAS approvals across six regulatory authorities (2020–2024)



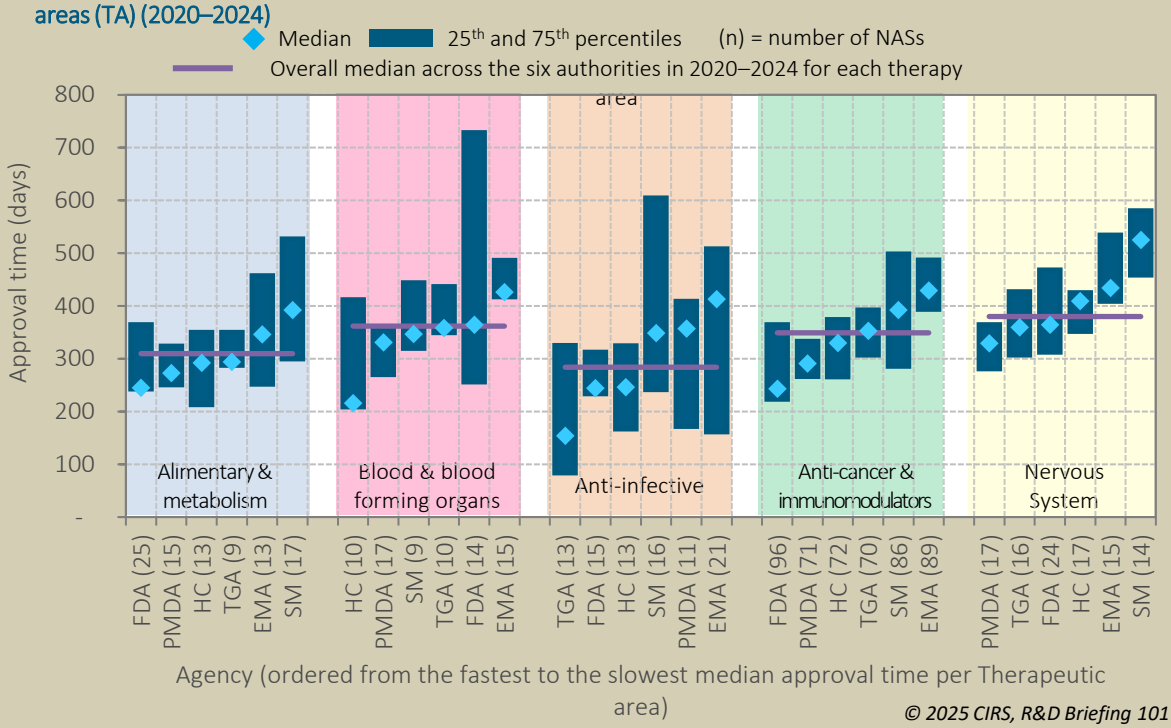
***Approval time** is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. **N1:** Overall approval time for 2024. **(N2):** Time from submission until the end of scientific assessment. **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 2024, a pattern that has been sustained over the past five years. Health Canada had the shortest median approval time for expedited reviews at 223 days, while TGA had the longest at 251 days (Fig. 6).

In 2024, the largest difference between expedited and standard medians was observed at Swissmedic (210 days), followed by Health Canada (154 days), FDA (122 days), TGA (119 days) and PMDA (77 days). At Swissmedic, the difference extended beyond scientific assessment, as expedited NAS approvals had a 55-day interval between the median approval time and the median time to the end of scientific assessment, whereas standard reviewed NAS approvals had 146 days for the same interval, suggesting a shorter labelling process when expedited review is used.

Therapeutic areas

Figure 7. Approval time variability for NAS approvals across six regulatory authorities by top five therapeutic areas (TA) (2020–2024)



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 2020 and 2024, anti-infective therapies had the shortest overall median approval time across the six authorities (284 days), followed by therapies for alimentary and metabolism (310 days), anti-cancer and immunomodulators (349 days), blood-related conditions (362 days), and nervous system disorders (380 days) (Fig. 7 & 8). Compared to previous briefings (R&D 93, 81, 85 and 88), the gap between the overall median approval time for anti-infective therapies and other therapeutic areas has widened, likely by the rapid approval of NASs for COVID-19 and HIV.

Alimentary and metabolism therapies kept their position as the second fastest-reviewed therapeutic area, followed by anti-cancer and immunomodulator therapies in third place. This ranking may be due to a shift in unmet medical needs. Notably, the proportion of alimentary and metabolism NASs reviewed through an expedited pathway increased from 24% in 2015–2019 to 45% in 2020–2024 (Fig. 10).

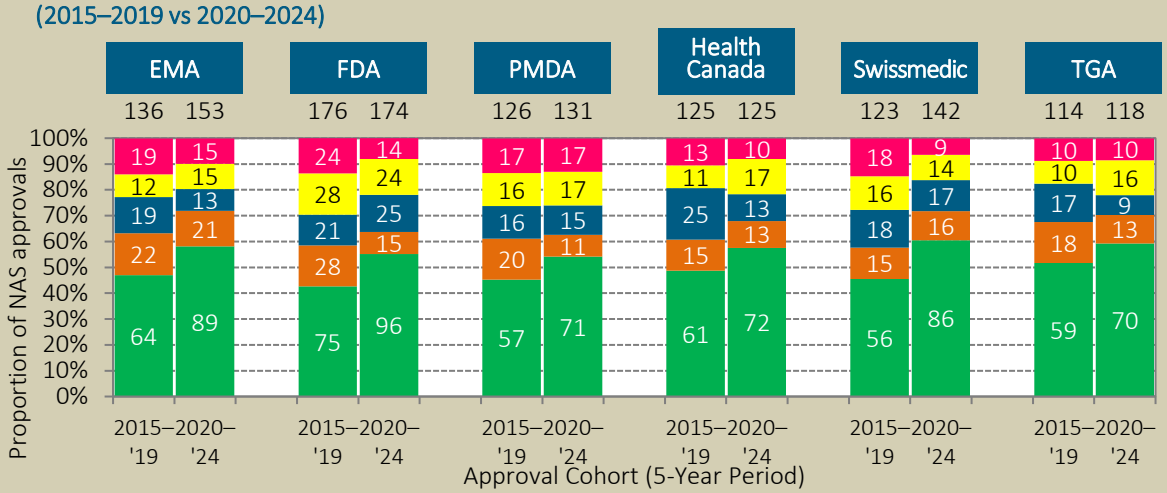
Figure 8. Overall median approval time and proportion of expedited-reviewed NAS approvals by top five TAs across six regulatory authorities (2020–2024)

© 2025 CIRS, R&D Briefing 101	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	346 (31%)	426 (0%)	413 (5%)	429 (8%)	434 (0%)
FDA	245 (72%)	364 (64%)	244 (93%)	243 (71%)	364 (50%)
PMDA	273 (60%)	331 (47%)	357 (55%)	291 (42%)	329 (24%)
Health Canada	292 (62%)	216 (60%)	246 (38%)	330 (18%)	409 (18%)
Swissmedic	392 (12%)	347 (33%)	349 (31%)	392 (27%)	525 (14%)
TGA	294 (0%)	359 (10%)	154 (23%)	353 (11%)	360 (6%)
Overall	310 (45%)	362 (36%)	284 (38%)	349 (31%)	380 (21%)

***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.*

Therapeutic areas *(cont.)*

Figure 9. Proportion of NAS approvals by top five therapeutic areas (TA) across six regulatory authorities (2015–2019 vs 2020–2024)



Therapy areas relate to the WHO ATC codes.

Out of the top five therapeutic areas, anti-cancer and immunomodulatory therapies have consistently accounted for the largest proportion of NAS approvals across all six regulatory authorities during the last decade. Their proportion increased from 47% in the 2015–2019 cohort to 57% in 2020–2024, reflecting an increase of 11 percentage points (pp), while the proportion of the other major therapeutic areas remained the same or showed modest declines over the same period (Fig. 9). Collectively, the top five therapeutic areas accounted for 74% of all NAS approvals between 2020 and 2024.

At the authority level, Swissmedic had the greatest increase in the proportion of anti-cancer and immunomodulatory therapy approvals (+15pp), followed by FDA (+13pp), EMA (+11pp), PMDA and Health Canada (both +9pp) and TGA (+8pp). In contrast, approvals for therapies targeting the nervous system saw more modest increases at Health Canada and TGA with +5pp each, while the proportions declined or remained stable at other authorities.

Figure 10. Comparison of the proportion of expedited NAS approvals across the top five therapeutic areas by six regulatory authorities: 2015–2019 vs. 2020–2024

© 2025 CIRS, R&D Briefing 101	Alimentary and metabolism		Blood and blood forming organs		Anti-infective		Anti-cancer and immuno-modulators		Nervous system	
	Proportion of expedited reviewed approvals 2015–2019 vs 2020–2024									
EMA	11%	31% ▲	16%	0% ▼	23%	5% ▼	13%	8% ▼	17%	0% ▼
FDA	52%	72% ▲	54%	64% ▲	82%	93% ▲	77%	71% ▼	46%	50% →
PMDA	44%	60% ▲	29%	47% ▲	60%	55% →	63%	42% ▼	19%	24% ▲
Health Canada	28%	62% ▲	23%	60% ▲	40%	38% →	20%	18% →	27%	18% ▼
Swissmedic	0%	12% ▲	0%	33% ▲	40%	31% ▼	32%	27% ▼	0%	14% ▲
TGA	6%	0% ▼	20%	10% ▼	0%	23% ▲	3%	11% ▲	0%	6% ▲
Overall	24%	45% ▲	26%	36% ▲	44%	38% ▼	36%	31% ▼	23%	21% →

▲ ≥ +5pp → Between –5pp & +5pp ▼ ≤ –5pp

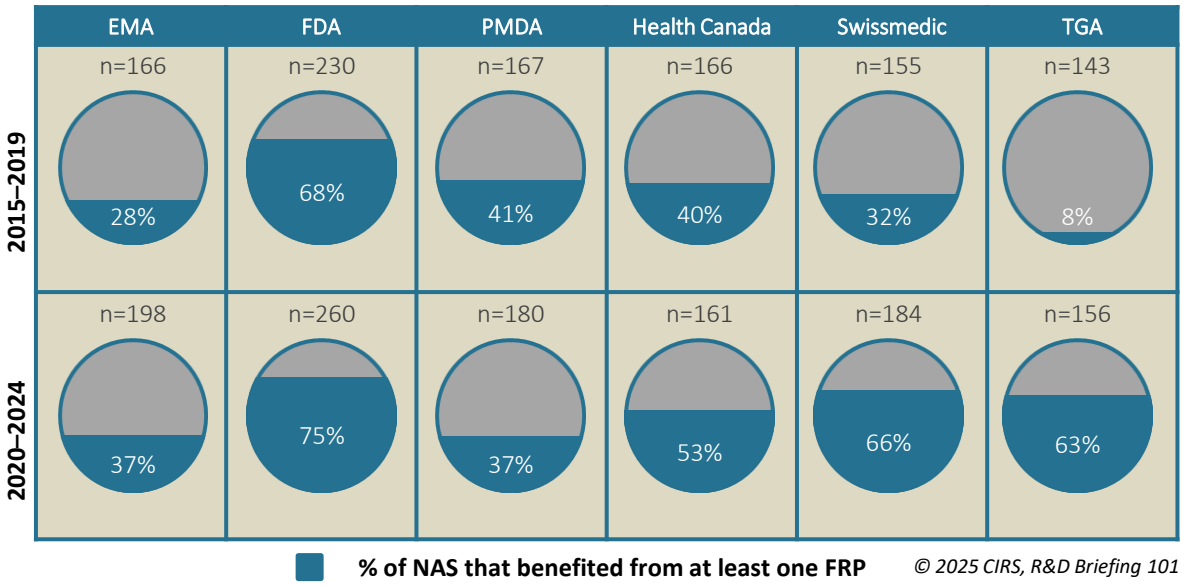
***Therapeutic areas** relate to the WHO ATC codes. Approval time is calculated from the date of submission to the date of approval by the agency. This time includes agency and company time. EMA approval time includes the EU Commission time. **Expedited review** refers to EMA's 'Accelerated Assessment'. 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.*

The use of expedited review pathways for NAS approvals increased in two of the five top therapeutic areas between 2015–2019 and 2020–2024: alimentary and metabolism therapies (from 24% to 45%) and blood and blood forming organs (from 26% to 36%) across all six regulatory authorities, suggesting a shift in unmet medical needs (Fig. 10). In alimentary and metabolism, all authorities except TGA recorded increases of 12pp to 34pp. In contrast, gains in blood-related therapies were concentrated within FDA, PMDA, Health Canada, and Swissmedic, ranging from 10pp to 37pp. Notably, Health Canada showed the largest increase in alimentary and one of the highest in blood therapies.

Focus on facilitated regulatory pathways (FRPs)

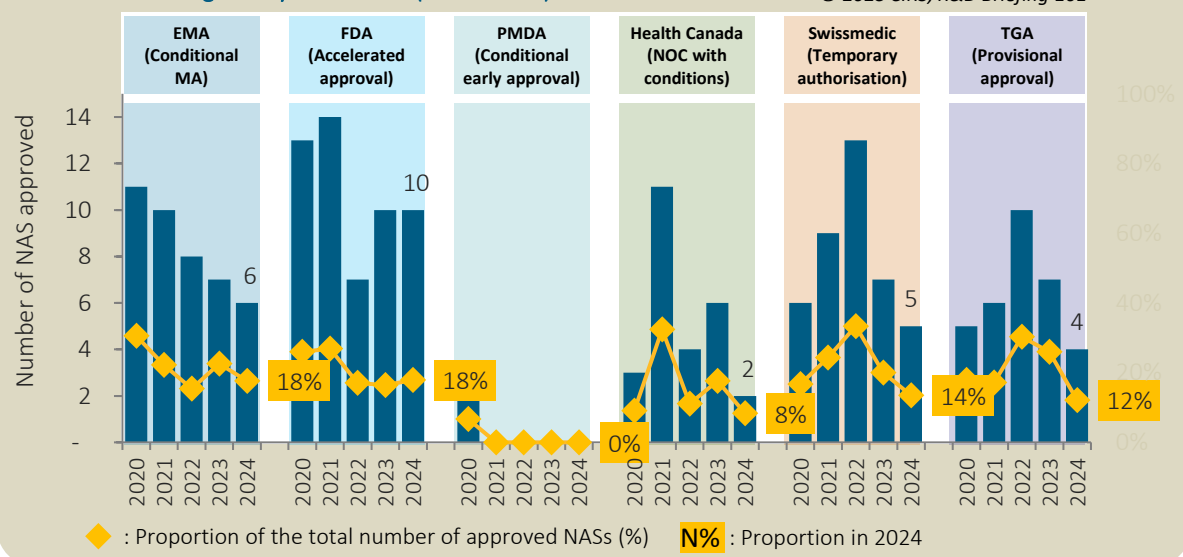
Over the last five years (2020–2024), the usage of facilitated regulatory pathways (FRPs, see p. 22 for definitions) has increased for most of the agencies compared with the beginning of the decade (2015–2019) (Fig. 11). FDA was the authority that most frequently used FRPs between 2020–2024, with 75% of NAS approvals involving at least one FRP, followed by Swissmedic (66%), TGA (63%), Health Canada (53%), PMDA and EMA (37% each). TGA was the authority that had the biggest increase in terms of the percentage of NAS approvals with FRPs, which reflects the implementation of the five FRPs by TGA (starting in 2017 with Priority review, Provisional approvals, Comparable overseas regulators (COR) review, Access Consortium, and Project Orbis). PMDA was the only authority where the proportion of NAS approvals with an FRP remained largely similar across periods, with only a minor decrease of 4 percentage points.

Figure 11. Proportion of NAS approvals across six regulatory authorities that benefited from at least one facilitated regulatory pathway (2015–2019 vs 2020–2024)



In 2024, the proportion of NAS approvals granted by conditional, temporary, provisional pathways was 18% for both EMA and FDA, 14% for Swissmedic, 12% for TGA and 8% for Health Canada (Fig. 12). The number of conditional/ accelerated/provisional approvals has generally fluctuated year on year in 2020–2024. In general, these types of approval pathways were faster than the overall median approval time (Fig. 13, on p. 9), which may be due to the use of expedited pathways.

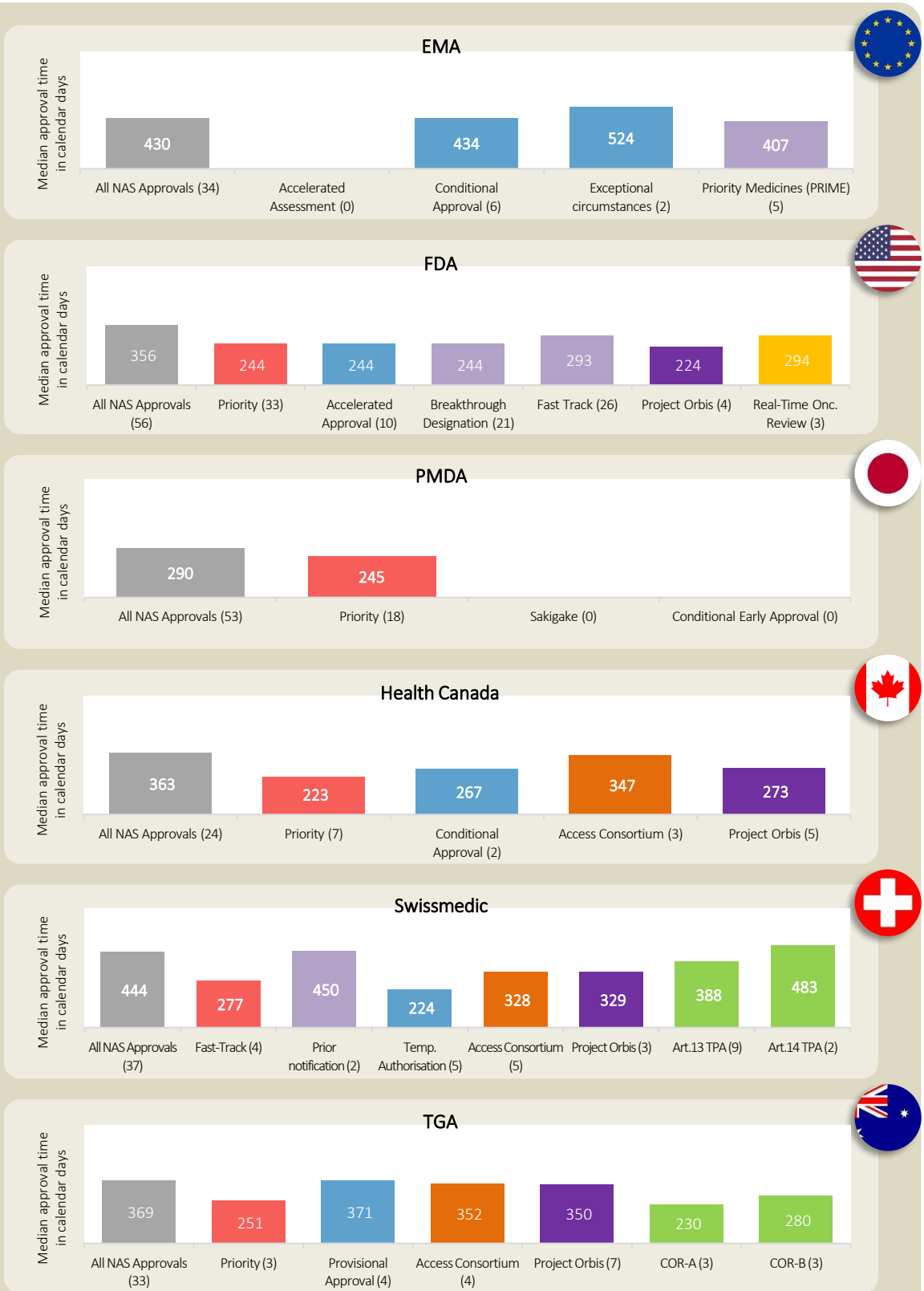
Figure 12. Number of NAS approvals granted through a conditional, temporary or provisional pathway across the six regulatory authorities (2015–2024)



The 2024 NAS median approval times for the different FRPs are illustrated on the next page (Fig. 13).

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

Figure 13. FRPs median approval timelines across six regulatory authorities — Focus on 2024



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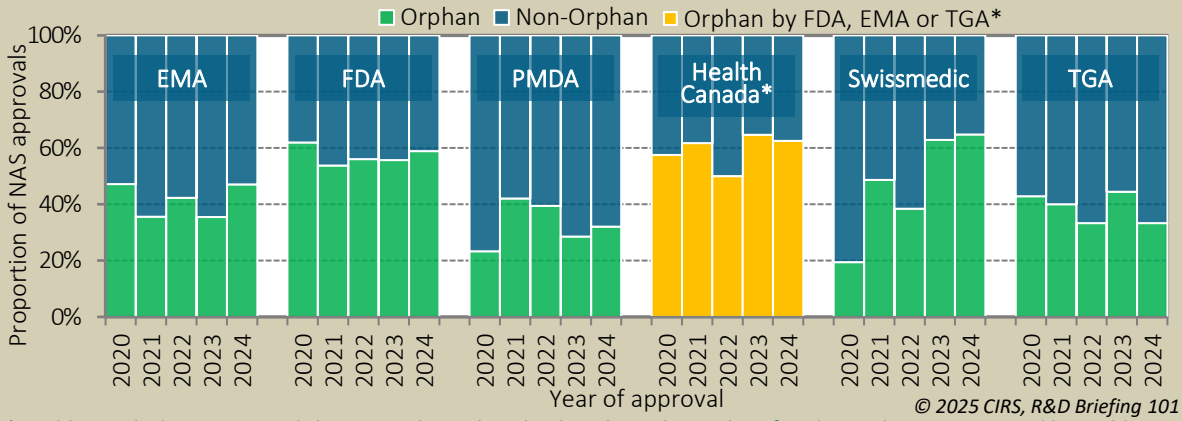
(n) = number of NASs

For FRP definitions, see p.22.

Orphan designations

Figure 14. Proportion of NAS approvals by orphan designation across six regulatory authorities (2020–2024)



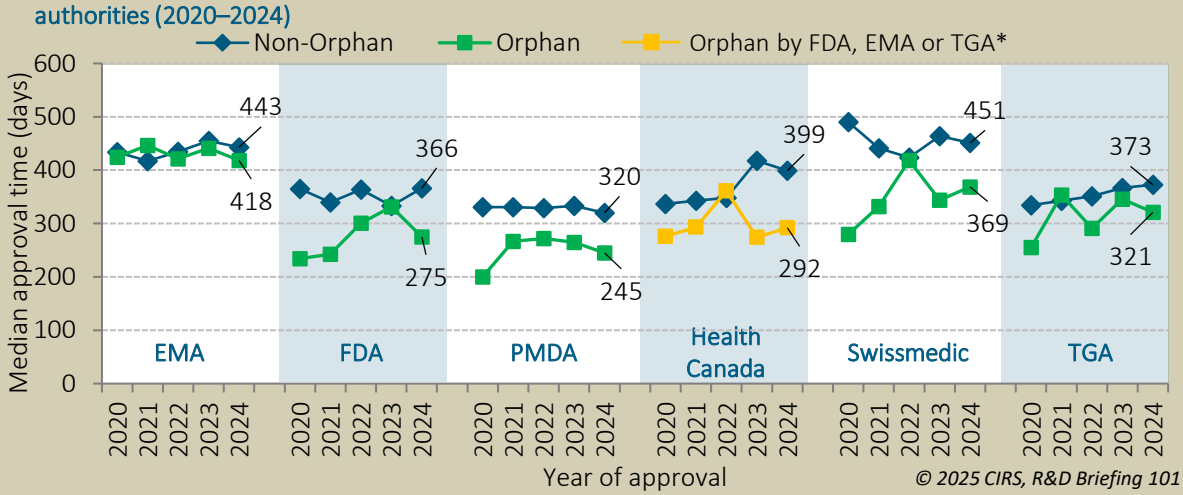
** Health Canada does not currently have an orphan policy; this data shows the number of medicines that were approved by Health Canada that were classified as orphan by either FDA, EMA or TGA.*

In 2024, the proportion of NAS approvals with an orphan designation was high across all authorities, with 65% for Swissmedic, 59% for FDA, 47% for EMA, 33% for TGA and 32% for PMDA (Fig. 14).

Over the 2020–2024 cohort, the proportion of NAS approvals with an orphan designation varied year-on-year but generally increased compared with 2015–2019. The largest increase was observed for Swissmedic (+12 percentage points, rising from 35% to 47%), followed by TGA (+10pp, from 28% to 38%), FDA (+9pp, from 48% to 57%), and EMA (+7pp, from 34% to 41%), while PMDA remained stable at 34%.

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 15. Trends in median approval time by orphan designation in NAS approvals across six regulatory authorities (2020–2024)



***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 2024, PMDA had the fastest median approval time for orphan products at 245 days, followed by FDA (275 days), TGA (321 days), Swissmedic (369 days), and EMA (418 days) (Fig. 15). The shorter timelines observed at PMDA likely reflect the authority's policy of automatically granting expedited review to orphan-designated applications, as part of its broader efforts to address unmet medical needs.

In 2024, FDA showed a difference in median approval times between orphan- and non-orphan NASs of 91 days, followed by Swissmedic (82 days), PMDA (75 days), TGA (52 days), and EMA (25 days). Health Canada does not currently have an orphan policy; however, for the NASs it approved in 2024 that were designated as orphan by either the FDA, EMA or TGA, the median approval time was 292 days.

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 (2015–2019 and 2020–2024) to identify trends.

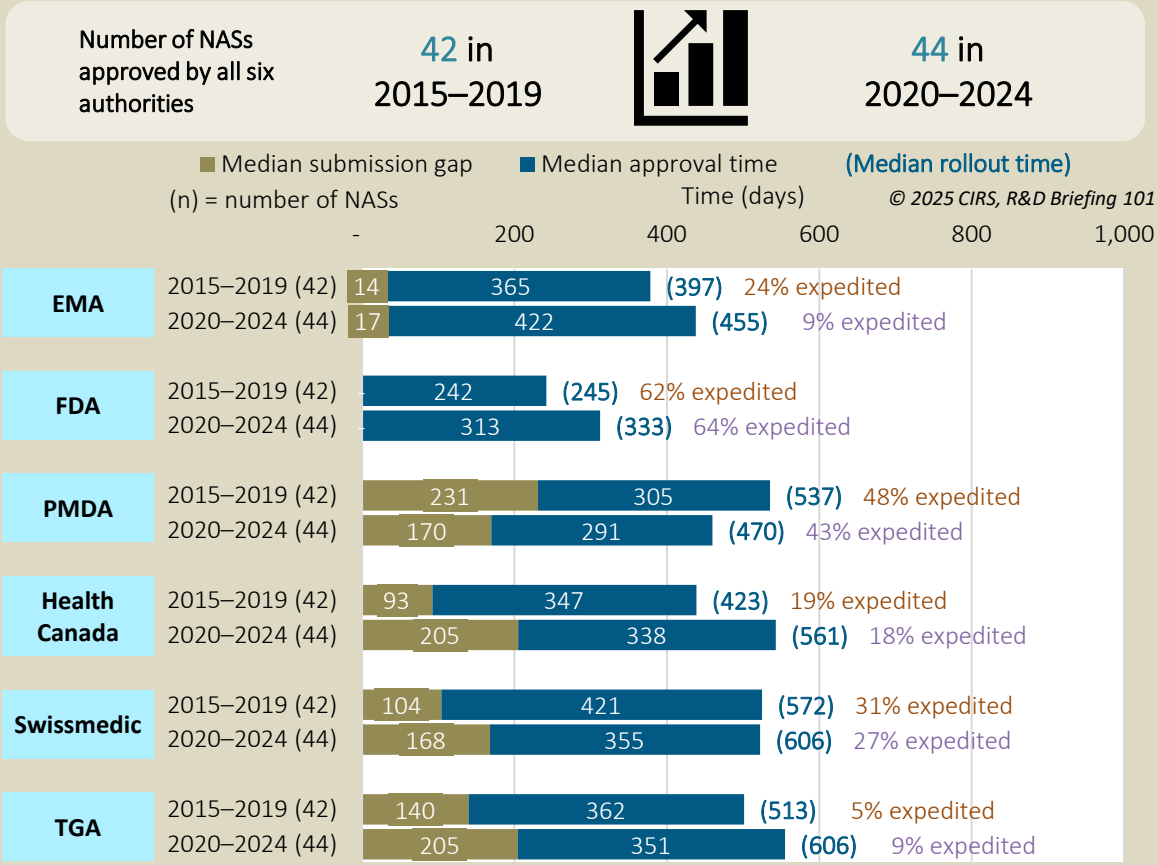
The number of NASs approved by all six authorities increased from 42 NASs in 2015–2019 to 44 NASs in 2020–2024, reversing the three-year decline reported in R&D Briefing 93, 88 and 85. This result is consistent with earlier analyses (see R&D Briefing 70 and 77) and suggests that the pace of internationalisation is stabilising.

The rollout time, consisting of the submission gap and approval time (Fig. 16), can be influenced by several factors such as company submission strategy and the use of expedited pathways to address unmet medical needs. The fastest overall median rollout time for the 2020–2024 cohort was observed for FDA with 333 days, reflecting early submissions and shorter review times linked to the high use of expedited reviews (64% of approved NASs). This was followed by EMA (455 days), PMDA (470 days), Health Canada (561 days), and both Swissmedic and TGA (606 days each). Compared with 2015–2019, rollout times decreased at PMDA (by 67 days), while increases were observed at Swissmedic (34 days), EMA (58 days), FDA (88 days), TGA (93 days), and Health Canada (138 days).

Between 2020 and 2024, submissions to FDA and EMA occurred almost simultaneously, with a median submission gap of just 17 days. Swissmedic and PMDA followed with longer, yet comparable, median gaps of 168 and 170 days, respectively. Health Canada and TGA had both the longest median gaps at 205 days.

Compared to 2015–2019, the data suggest a shift in submission patterns: companies submitted to PMDA 67 days earlier in 2020–2024, aligning its timeline closer to that of Swissmedic, Health Canada, and TGA. However, the median submission gaps to these latter three authorities increased by 64, 112, and 65 days, respectively. Additionally, comparisons with R&D Briefing 77 results confirm the steady increase in the median submission gaps for Health Canada, Swissmedic and TGA over the last 15 years.

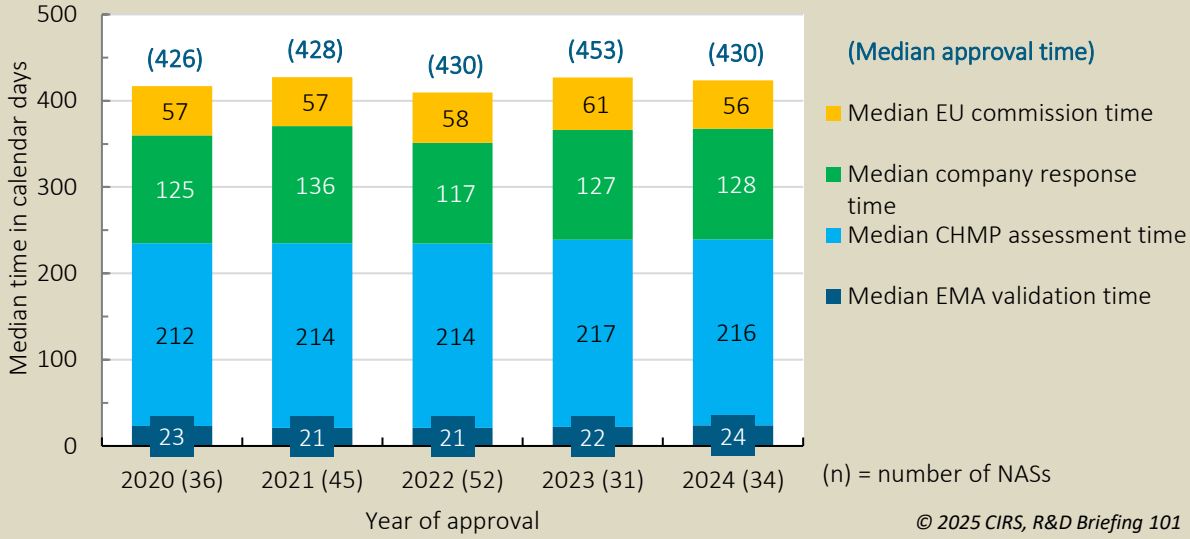
Figure 16. Median submission, approval, and rollout timelines and expedited review uptake for NASs approved by all six authorities (2015–2019 vs 2020–2024)



***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

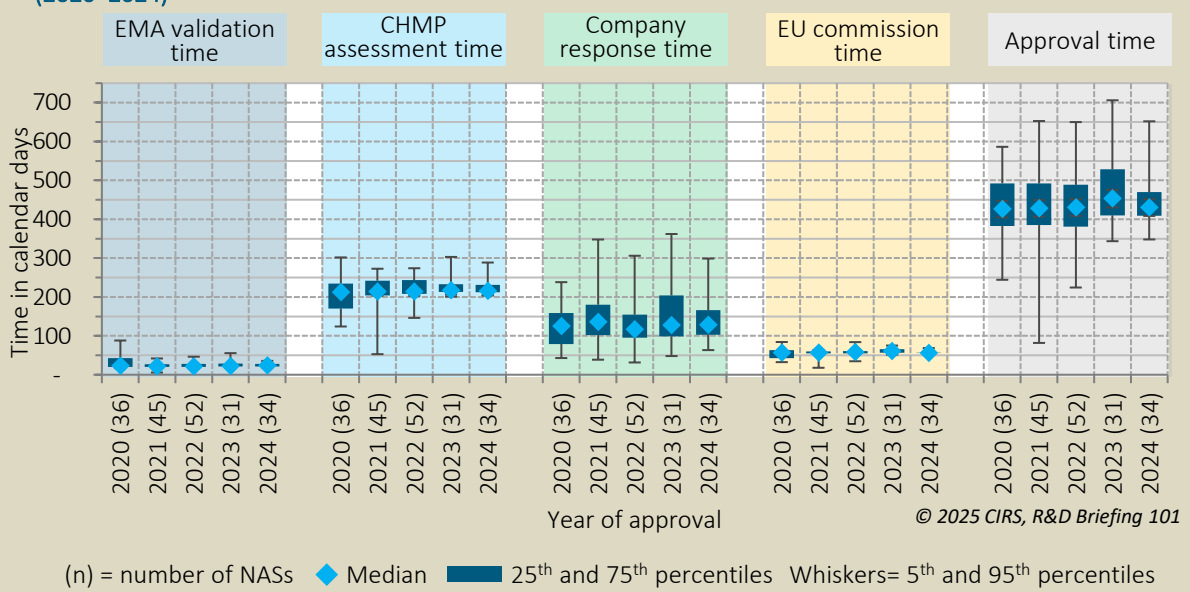
Figure 17. Median timelines for key intervals in the EU centralised marketing authorisation process for NASs by year of approval (2020–2024)



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 2020 to 2024, reflecting the structured and legislated timelines of the centralised procedure (Fig. 17 & 18). Over the five years, EMA's median approval time remained consistent, ranging from a low of 426 days in 2020 to a high of 453 days in 2023. In 2024, the median durations for each key interval were as follows: validation time accounted for 6% of the total (24 days), CHMP assessment accounted for 51% (216 days), company response time accounted for 30% (128 days), and European Commission decision time accounted for 13% (56 days).

Notably, the EMA's approval time IQR narrowed from 110 days in 2020 to 61 days in 2024, indicating increased consistency (Fig. 18). A similar trend was observed across the key process intervals: the CHMP assessment IQR narrowed from 64 to 19 days, the company response time IQR narrowed from 80 to 63 days, and the European Commission decision time IQR narrowed from 20 to just 1 day.

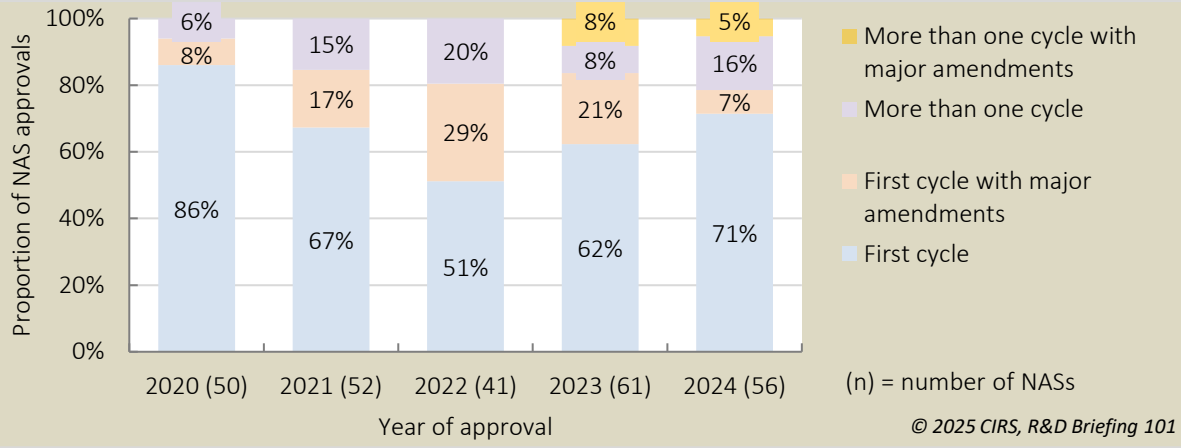
Figure 18. Variability in timelines for key intervals of the EU centralised marketing authorisation procedure (2020–2024)



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.* ***Total approval time*** *is calculated as the sum of these four periods.*

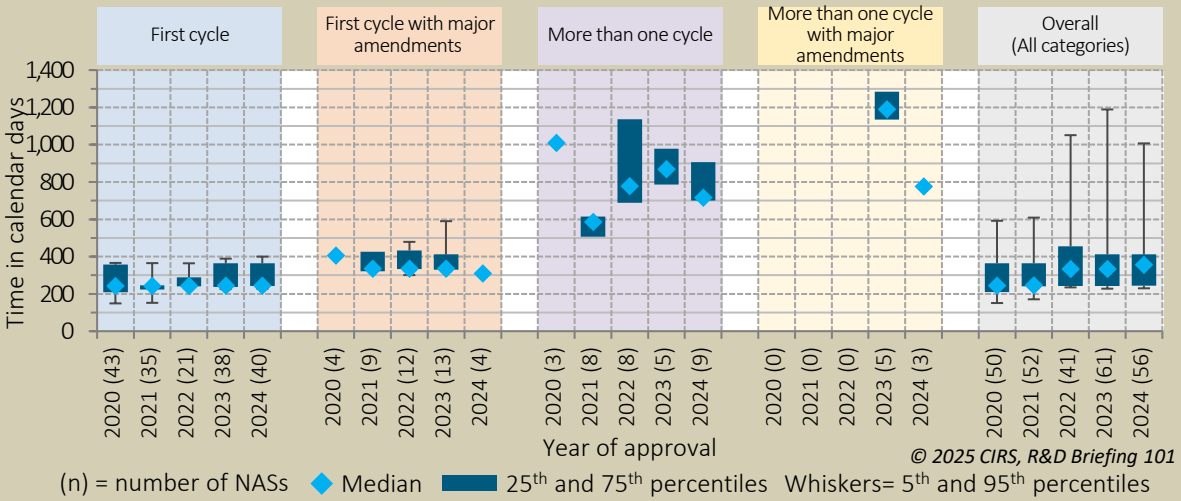
Focus on FDA's review cycles and major amendments involvement

Figure 19. Distribution of FDA NAS approvals by review cycle and involvement of major amendments (2020–2024)



Although the proportion of first-cycle NAS approvals at the FDA declined to a low of 51% in 2022, it has since shown a steady recovery, increasing to 62% in 2023 and then 71% in 2024 (Fig. 19). Although major amendments were used more often in 2022 than in any other year, they helped sponsors fix deficiencies early and avoid receiving a Complete Response Letter. This approach helped the FDA maintain around 80% of NAS approvals being granted within the first review cycle. While no NASs were approved after multiple review cycles involving major amendments between 2020 and 2022, such approvals were granted in 2023 and 2024, accounting for 8% and 5%, respectively.

Figure 20. Variability in FDA NAS approval times across review cycles and major amendment involvement (2020–2024)



***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.*

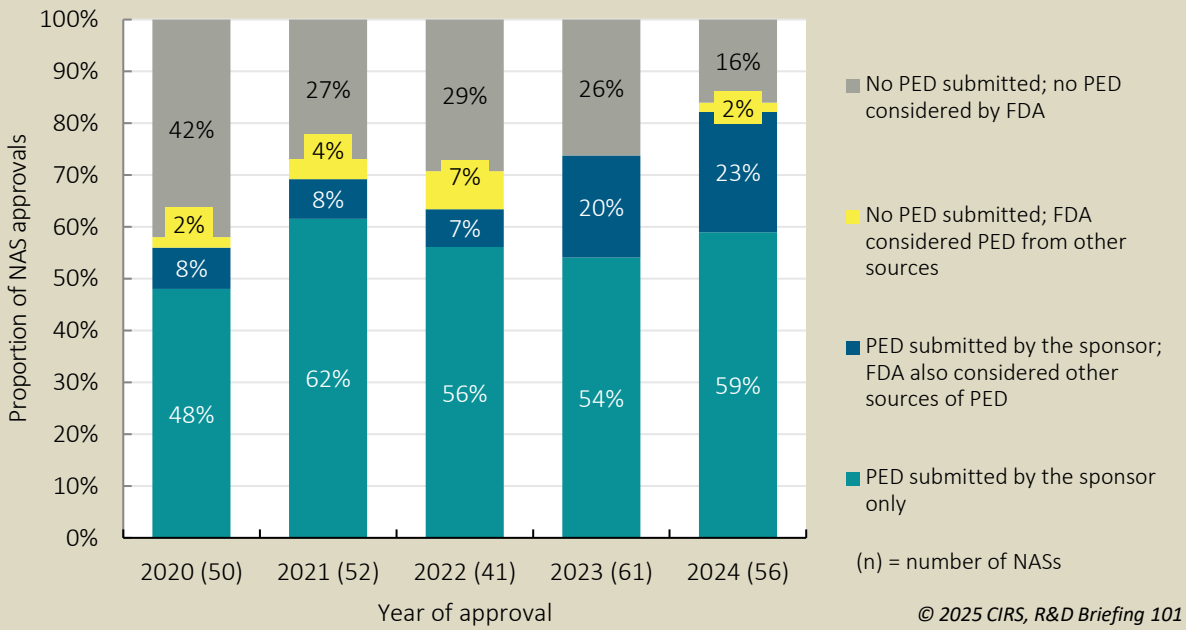
FDA approval times for NASs between 2020 and 2024 varied markedly based on the number of review cycles and the use of major amendments (Fig. 20). NASs approved in the first review cycle without major amendments had the shortest and most consistent timelines, with median approval times of 242 days in both 2021 and 2022, and 244 days in 2023 and 2024. IQRs were similarly stable, ranging from 22 days in 2021 to 148 days in 2020. The narrowest IQR observed in 2021 coincides with one of the highest levels of Priority Review use, as shown in Figure 6, suggesting that increased use of expedited pathways led to a smaller range of timelines. In contrast, NASs approved after more than one cycle, particularly those involving major amendments, often exceeded 500 calendar days and exhibited the widest 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 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 21 summarises the use of PED in NAS approvals between 2020 and 2024.

Figure 21. Inclusion and consideration of patient experience data in FDA NAS approvals (2020–2024)



The proportion of NASs that included and/or considered PED increased steadily from 58% in 2020 to 84% in 2024, reflecting a consistent upward trend over the five-year period (Fig. 21).

This growth was mainly driven by an increase in application where PED was *"both submitted by the sponsor and where additional PED was identified and considered by FDA",* increasing from 8% in 2020 to 23% in 2024. Approvals based on PED submitted by the sponsor (where no additional PED was identified by FDA) also increased, from 48% in 2020 to 59% in 2024. In contrast, cases where only external PED was considered by FDA (i.e. data that was not submitted in the application, but was considered by FDA in the scientific review as described in the PED table) varied between 2020–2024, but remained low accounting for just 2% of approvals in 2024. These upward trends in the use of PED align with the FDA's patient-focused drug development initiatives and reflect a broader interest in incorporating patient perspectives into benefit–risk assessments. Nonetheless, the lack of publicly available detail 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 2024 by the six authorities

This table summarises approval times for NASs approvals granted in 2024 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	34	56	53	24	37	33
NAS median overall approval time (days)	430	356	290	363	444	369
By biologics (days)	429	342	271	292	366	375
By chemicals (days)	433	356	312	377	451	366
By standard review (days)	430	366	321	377	454	370
By expedited review (days)	-	244	245	223	245	251
By orphans (days)	418	275	245	292*	369	321
By anticancer and immuno-modulators (days)	428	341	296	363	396	360

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 2024, Health Canada approved 15 NASs classified as orphan by either the FDA, EMA, or TGA, with a median approval time of 292 days.*

EMA APPROVED A TOTAL OF 34 NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 430 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 372 DAYS

THE MEDIAN EU COMMISSION TIME WAS 56 DAYS, THE EMA REVIEW TIME 242 DAYS AND THE COMPANY TIME 128 DAYS

Type of Medicine

16 BIOLOGIC NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 429 DAYS

18 CHEMICAL NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 433 DAYS

17 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 428 DAYS

17 NASs IN OTHER THERAPY AREAS APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 435 DAYS

Designation and Review Type

NO EXPEDITED NAS APPROVALS WERE GRANTED IN 2024

16 ORPHAN NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 418 DAYS; THIS IS 25 DAYS FASTER THAN THE MEDIAN OF THE 18 NON-ORPHAN NASs IN 2024

Availability by EMA

12% OF THE NASs APPROVED IN 2024 BY EMA WERE APPROVED FIRST BY THE AGENCY OR WITHIN ONE MONTH OF FIRST APPROVAL BY ANY OF THE OTHER AGENCIES

88% OF THE NASs APPROVED IN 2024 BY EMA WERE APPROVED BY ANY OF THE OTHER AGENCIES FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY THE AGENCY

THE MEDIAN SUBMISSION GAP TO EMA FOR THESE NASs WAS 98 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.

FDA (CDER AND CBER) APPROVED A TOTAL OF 56 NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 356 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 356 DAYS

79% OF THE NAS APPROVALS WERE GRANTED BY THE FDA IN THE FIRST SCIENTIFIC REVIEW CYCLE

Type of Medicine

22 BIOLOGIC NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 342 DAYS

34 CHEMICAL NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 356 DAYS

12 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 341 DAYS

44 NASs IN OTHER THERAPY AREAS APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 358 DAYS

Designation and Review Type

33 EXPEDITED NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 244 DAYS; THIS IS 122 DAYS FASTER THAN THE MEDIAN OF THE 23 STANDARD NASs IN 2024

33 ORPHAN NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 275 DAYS; THIS IS 91 DAYS FASTER THAN THE MEDIAN OF THE 23 NON-ORPHAN NASs IN 2024

Availability by FDA

75% OF THE NASs APPROVED IN 2024 BY FDA WERE APPROVED FIRST BY THE AGENCY OR WITHIN ONE MONTH OF FIRST APPROVAL BY ANY OF THE OTHER AGENCIES

25% OF THE NASs APPROVED IN 2024 BY FDA WERE APPROVED BY ANY OF THE OTHER AGENCIES FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY THE AGENCY

THE MEDIAN SUBMISSION GAP TO FDA FOR THESE NASs WAS 19 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.

PMDA APPROVED A TOTAL OF 53 NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 290 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 267 DAYS

Type of Medicine

25 BIOLOGIC NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 271 DAYS

28 CHEMICAL NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 312 DAYS

22 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 296 DAYS

31 NASs IN OTHER THERAPY AREAS APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 283 DAYS

Designation and Review Type

18 EXPEDITED NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 245 DAYS; THIS IS 76 DAYS FASTER THAN THE MEDIAN OF THE 35 STANDARD NASs IN 2024

17 ORPHAN NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 245 DAYS; THIS IS 75 DAYS FASTER THAN THE MEDIAN OF THE 36 NON-ORPHAN NASs IN 2024

Availability by PMDA

23% OF THE NASs APPROVED IN 2024 BY PMDA WERE APPROVED FIRST BY THE AGENCY OR WITHIN ONE MONTH OF FIRST APPROVAL BY ANY OF THE OTHER AGENCIES

77% OF THE NASs APPROVED IN 2024 BY PMDA WERE APPROVED BY ANY OF THE OTHER AGENCIES FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY THE AGENCY

THE MEDIAN SUBMISSION GAP TO PMDA FOR THESE NASs WAS 1026 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.

Focus: NAS approvals at Health Canada in 2024 R&D Briefing 101

HEALTH CANADA APPROVED A TOTAL OF 24 NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 363 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 363 DAYS

Type of Medicine

9 BIOLOGIC NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 292 DAYS

15 CHEMICAL NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 377 DAYS

12 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 363 DAYS

12 NASs IN OTHER THERAPY AREAS APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 372 DAYS

Designation and Review Type

7 EXPEDITED NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 223 DAYS; THIS IS 154 DAYS FASTER THAN THE MEDIAN OF THE 17 STANDARD NASs IN 2024

HEALTH CANADA DOES NOT HAVE AN ORPHAN POLICY; HOWEVER, 15 NASs THAT WERE CLASSIFIED AS ORPHAN BY EITHER FDA, EMA OR TGA WERE APPROVED BY HEALTH CANADA IN 2024, WITH A MEDIAN APPROVAL TIME OF 292 DAYS

Availability by Health Canada

8% OF THE NASs APPROVED IN 2024 BY HEALTH CANADA WERE APPROVED FIRST BY THE AGENCY OR WITHIN ONE MONTH OF FIRST APPROVAL BY ANY OF THE OTHER AGENCIES

92% OF THE NASs APPROVED IN 2024 BY HEALTH CANADA WERE APPROVED BY ANY OF THE OTHER AGENCIES FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY THE AGENCY

THE MEDIAN SUBMISSION GAP TO HEALTH CANADA FOR THESE NASs WAS 289 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.

SWISSMEDIC APPROVED A TOTAL OF 37 NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 444 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 288 DAYS

Type of Medicine

16 BIOLOGIC NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 366 DAYS

21 CHEMICAL NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 451 DAYS

19 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 396 DAYS

18 NASs IN OTHER THERAPY AREAS APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 447 DAYS

Designation and Review Type

8 EXPEDITED NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 245 DAYS; THIS IS 209 DAYS FASTER THAN THE MEDIAN OF THE 29 STANDARD NASs IN 2024

24 ORPHAN NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 369 DAYS; THIS IS 82 DAYS FASTER THAN THE MEDIAN OF THE 13 NON-ORPHAN NASs IN 2024

Availability by Swissmedic

8% OF THE NASs APPROVED IN 2024 BY SWISSMEDIC WERE APPROVED FIRST BY THE AGENCY OR WITHIN ONE MONTH OF FIRST APPROVAL BY ANY OF THE OTHER AGENCIES

92% OF THE NASs APPROVED IN 2024 BY SWISSMEDIC WERE APPROVED BY ANY OF THE OTHER AGENCIES FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY THE AGENCY

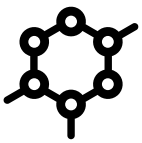
THE MEDIAN SUBMISSION GAP TO SWISSMEDIC FOR THESE NASs WAS 471 DAYS

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.

TGA APPROVED A TOTAL OF 33 NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 369 DAYS AND A MEDIAN TIME TO END OF SCIENTIFIC ASSESSMENT OF 369 DAYS

Type of Medicine

10 BIOLOGIC NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 375 DAYS



23 CHEMICAL NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 366 DAYS

13 ANTI-CANCER AND IMMUNOMODULATOR NASs APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 360 DAYS

20 NASs IN OTHER THERAPY AREAS APPROVED IN 2024, WITH A MEDIAN APPROVAL TIME OF 371 DAYS

Designation and Review Type

3 EXPEDITED NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 251 DAYS; THIS IS 119 DAYS FASTER THAN THE MEDIAN OF THE 30 STANDARD NASs IN 2024

11 ORPHAN NASs IN 2024, WITH A MEDIAN APPROVAL TIME OF 321 DAYS; THIS IS 52 DAYS FASTER THAN THE MEDIAN OF THE 22 NON-ORPHAN NASs IN 2024

Availability by TGA

9% OF THE NASs APPROVED IN 2024 BY TGA WERE APPROVED FIRST BY THE AGENCY OR WITHIN ONE MONTH OF FIRST APPROVAL BY ANY OF THE OTHER AGENCIES

91% OF THE NASs APPROVED IN 2024 BY TGA WERE APPROVED BY ANY OF THE OTHER AGENCIES FIRST OR MORE THAN ONE MONTH BEFORE BEING APPROVED BY THE AGENCY

THE MEDIAN SUBMISSION GAP TO TGA FOR THESE NASs WAS 283 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.

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

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	

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.

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.

Development time
Time calculated from the date of approval/ submission of the Investigational New Drug (IND) application to the date of submission of the NAS application in FDA

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)

*The full list of NASs approved by each jurisdiction in 2024 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.

Rollout time
Time calculated from date of submission at the first regulatory agency to the date of regulatory approval at 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 2023. Company R&D spending data was obtained from the Pharm Exec Top 50 Companies (2024) available at https://www.pharmexec.com/view/2024-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.

Report prepared by

Juan Lara, Senior Research Analyst

Adem Kermad, Principal Research Analyst

Magda Bujar, PhD, Associate Director, Regulatory Programme & Strategic Partnerships

Neil McAuslane, PhD, Scientific Director

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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 identify and apply scientific principles for the purpose of advancing regulatory and health technology assessment (HTA) policies and processes. 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.

Email: cirs@cirsci.org
Website: www.cirsci.org
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