Executive Summary – Benchmarking 2025

Comparison of Swiss approval times for human medicines with the EU and the USA

Abstract

For the thirteenth time in succession, Swissmedic, the Swiss authority for the authorisation and monitoring of therapeutic products, and the Swiss pharmaceutical industry associations (ASSGP, Intergenerika, Interpharma, scienceindustries and vips) have conducted a benchmarking study analysing the times required to authorise human medicinal products in Switzerland and comparing them with the equivalent times for the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA). The results provide a factual basis for the ongoing dialogue between Swissmedic and the pharmaceutical industry. They help identify and exploit the potential for improvements in the authorisation processes for human medicinal products.

The analysis is based on new applications for new active substances (NA NAS), known active substances (KAS), and biosimilars, as well as additional indications (AIs) and extensions for new dosage forms. The analysis of the throughput times (time between the date of submission and the date of authorisation) in Switzerland considered all completed applications with a positive decision in 2025 (NA NAS: n=40, AIs: n=109, KAS: n=150, extensions: n=28, biosimilars: n=24). The data for the Swiss procedures originate directly from Swissmedic. The NA NAS data for the international comparison of the authorisation times were obtained from Swissmedic's own databases and public sources of the EMA and FDA. The AI data from the EMA and FDA were provided by the participating companies and matched to the Swissmedic data.

Half of all NA NAS in 2025 were authorised in an accelerated authorisation procedure[3], compared to 29% of AIs. The median national throughput time across all procedures for the NA NAS (n=40) was 392 calendar days (CDs), 12% shorter than in 2024, while the corresponding time for AIs (n=109) was 331 CDs (+4%).

Compared with the previous year, throughput times for Swissmedic authorisation procedures followed divergent trends: Whereas NA NAS in procedures with standard time limits (standard procedure and procedure according to Art. 13 TPA) were authorised slightly faster than in the previous year, the throughput time was slightly longer for the accelerated procedures[3] (pooled). The throughput time for AIs under the standard procedure and the Orbis Type A procedure was slightly longer compared to 2024, while the time was slightly shorter for applications under Art. 13 TPA and in the Access procedure.

Internationally, the Swiss throughput time for NA NAS (all procedures, 392 CDs, n=40) was 7% shorter compared to the EMA (420 CDs, n=38) and 47% longer compared to the FDA (266 CDs, n=36). For AIs (all procedures, 331 CDs, n=109), the Swissmedic throughput time was 7% longer compared to the EMA (309 CDs, n=64) and 81% longer compared to the FDA (183 CDs, n=59).

The submission gap for NA NAS continued to widen in 2025 (all procedures): Compared to the EMA, the gap was 362 CDs (n=38, +61%) and therefore almost as wide as the submission gap of 405 CDs (n=36, +25%) compared to the FDA. The approval gaps were 212 CDs (EMA: -3%) and 485 CDs (FDA: +45%).

For AIs, the submission and approval gaps (all procedures) grew wider since 2024 compared to both the EMA and the FDA: compared to the EMA the submission gap was 93 CDs (n=64) and therefore almost half as wide as in the previous year (-49%); compared to the FDA the submission gap was 142 CDs (-37%, n=59). The approval gaps were 137 CDs (EMA: -33%) and 304 CDs (FDA: -20%).

In 2025, 20% and 52% more new applications, respectively, were authorised for KAS without innovation (n=109) and KAS with innovation (n=41) compared to the previous year. The throughput times for applications under Art. 13 TPA for KAS without innovation and KAS with innovation were 33% and 17% shorter, respectively, than those employing the standard procedure.

Across all application types, the percentage of applications subject to a formal objection rose from 43% to 47%, whereas the percentage of applications requiring a text review letter fell from 29% to 20%.

Summary of the report

Methods

Benchmarking study inclusion criteria

The benchmarking study included new applications for new active substances (NA NAS), known active substances (KAS) with or without innovation, biosimilars, herbal medicinal products under the simplified procedure (NA herbal medicinal products), as well as additional indications (AIs) and extensions for new dosage forms that were authorised for the Swiss market in 2025.

Procedure

Swissmedic forwarded the national data for all applications that qualified for inclusion to the market research agency intervista[1].

In order to achieve a larger and more representative sample of the international data, for the first time all of the international NA NAS data for 2025 were obtained by Swissmedic from publicly accessible EMA and FDA databases.

For AIs, as before, the participating companies also sent the EMA and FDA data for their authorisation applications to intervista, which then analysed the data.

As regards the analyses for the international comparison of specific Swissmedic procedure types, it should be noted that the respectively matched EMA and FDA applications were not necessarily processed in a similar procedure type by the EMA or the FDA.

Since the figures presented in some of the analyses are based on very small sample sizes, the corresponding results should be viewed as purely descriptive and are of limited value for trend analyses or robust year-on-year comparisons. Percentage changes were therefore not calculated for analyses with fewer than 5 applications.

Notes on the calculation

The throughput time refers to the period between the date of submission to the respective authority and the date of authorisation by that authority. The term submission gap describes the period between the date of submission to the partner authority and the date of submission to Swissmedic, whereas the term approval gap is defined as the time difference between the date of authorisation by the partner authority and the date of authorisation by Swissmedic. The submission date is excluded in each case, and the number of calendar days (CDs) is reported as the median.

[1] intervista | The Swiss market research institute | B2B and B2C

New applications for new active substances (NA NAS)

Authorisation procedures

Swissmedic authorised a total of 40 NA NAS applications in 2025, representing a reduction of 13% compared to 2024.[2]

The proportion of NA NAS applications authorised in an accelerated authorisation procedure[3] increased from 41% to 50% (n=20) compared to the previous year. Two of these applications were additionally authorised in the reliance procedure under Art. 13 TPA.

The proportion of international Orbis and Access applications (pooled), in particular, rose from 17% (n=8) to 25% (n=10), and Access procedures (n=8) were used much more frequently than Orbis ones (Type A: n=1, Type B: n=1).

The percentage of NA NAS applications authorised under Art. 13 TPA fell from 28% to 23% (n=9) compared to the previous year.

Milestone analysis

The proportion of formal objections (FOs) rose from 26% in 2024 to 37% in 2025. 18% of the applications did not require a List of Questions (LoQ), including 6 under Art. 13 TPA and 1 application under Art 14 para. 1 let. a$^{bis\text{-}quater}$ TPA. The percentage of applications without an additional text review letter (TRL) increased from 63% to 71% compared to the previous year.

Throughput times

In 2025, the national throughput time across all procedures for the 40 NA NAS was 392 calendar days (CDs), 52 CDs (12%) shorter than in 2024 (445 CDs). The throughput times of the EMA and FDA increased respectively by 2% to 420 CDs (n=38) and by 9% to 266 CDs (n=36) compared to 2024.

Internationally, the Swiss throughput time for NA NAS (all procedures) was 7% shorter compared to the EMA (420 CDs) and 47% longer compared to the FDA (266 CDs, Figure 1). Swissmedic's throughput time for NA NAS submitted to all three authorities (n=36) was 386 CDs, 8% shorter than for the EMA (420 CDs) and 45% longer than for the FDA (266 CDs).

Year-on-year the following developments were observed in respect of throughput times: The throughput times for NA NAS under the standard procedure decreased compared to 2024 (n=12, 480 CDs, -8%). The throughput time for NA NAS under Art. 13 TPA was much shorter overall than in 2024 (n=13, 307 CDs, -21%), thanks to reductions in both the companies' time (from 150 to 132 CDs) and Swissmedic's time (from 239 to 175 CDs). The throughput times for FTPs (n=6, 288 CDs, +4%) have increased slightly. For the Access procedures, the throughput time was longer compared to 2024 (n=8, 395 CDs, +20%). With the exception of Access applications, the time limits for all procedures were observed both by Swissmedic and the applicants.

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[2] Authorisations of human medicinal products with a new active substance and additional indications 2025 Swissmedic, Bern, CH.

[3] These include the fast-track authorisation procedure (FTP), the procedure with prior notification (PPN), the temporary authorisation procedure and the international procedures according to Orbis and Access.

New applications for new active substances: throughput times
All procedures (2022 – 2025)

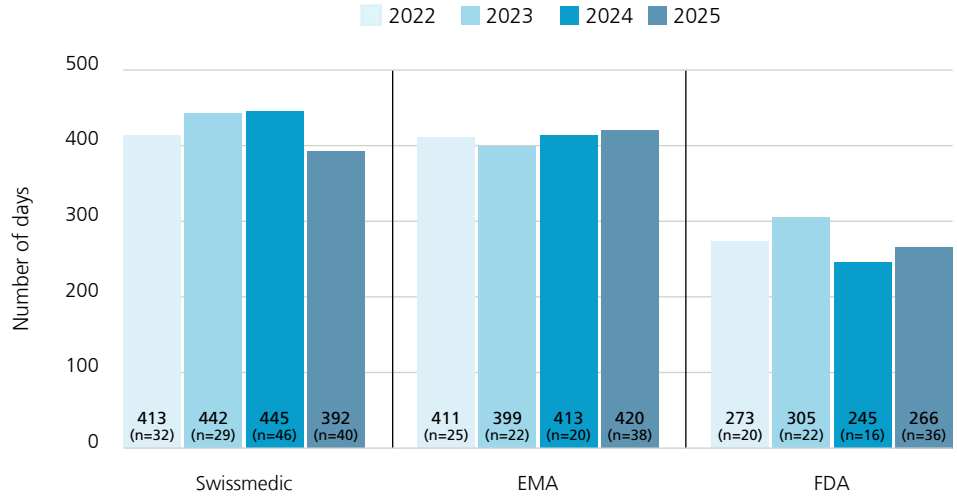

Figure 1: Comparison of throughput times of Swissmedic, the EMA and the FDA for new applications for new active substances (NA NAS) across all procedures, 2022 – 2025 (median values, n: number of applications).

Submission and approval gaps

In 2025, data sets for the analysis of the submission and approval gaps were available for 38 NA NAS for comparison with the EMA and 36 NA NAS for comparison with the FDA.

Compared with the EMA, the submission gap for NA NAS across all procedures rose by 61% compared with the previous year, from 225 CDs to 362 CDs, whereas the approval gap remained almost unchanged at 212 CDs (-3%, see Figure 2). Much narrower submission gaps were apparent for the Access procedures (66 CDs, n=8) and the Orbis Type A application (0 CDs, n=1). The approval gaps were also correspondingly narrower, at 17 CDs (Access) and -168 CDs (Orbis Type A). At 610 CDs and 511 CDs, respectively, the submission and approval gaps compared with the EMA were particularly wide for applications under Art. 13 TPA (n=9).

Compared with the FDA, the submission gap for NA NAS across all procedures widened by 25% compared with the previous year, from 323 CDs to 405 CDs, while the approval gap widened by 45%, from 335 CDs to 485 CDs. The comparisons with the FDA also showed much narrower submission gaps for the Access procedures (79 CDs, n=8) and the Orbis Type A application (33 CDs, n=1). The approval gaps were also correspondingly narrower, at 128 CDs and 113 CDs, respectively. At 460 CDs and 601 CDs, respectively, the submission and approval gaps compared with the FDA were likewise particularly wide for applications under Art. 13 TPA (n=8).

New applications for new active substances: submission and approval gaps
All procedures (2023 – 2025)

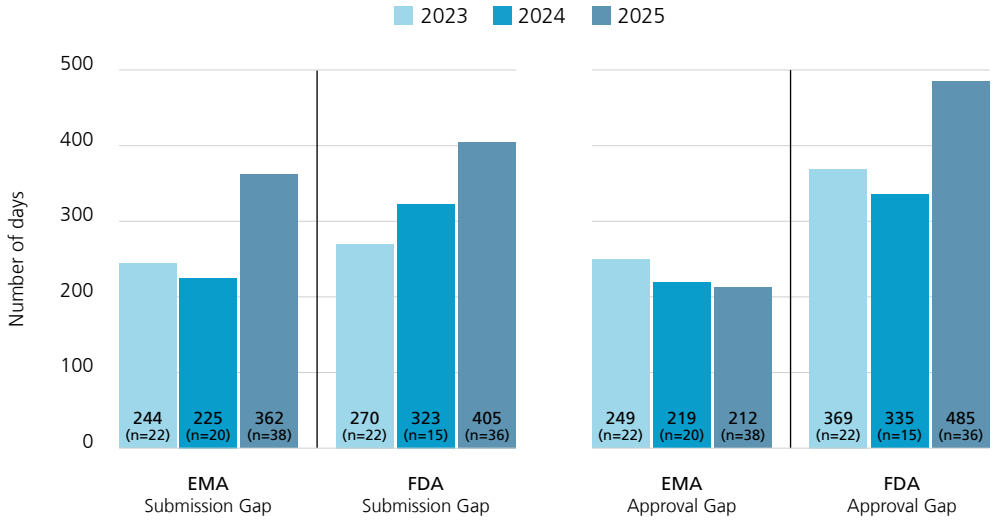

Figure 2: NA NAS (all procedures): median values for the Swissmedic submission and approval gaps compared with the EMA and FDA, 2023 – 2025 (n: number of applications).

Additional indications (AIs)

Authorisation procedures

In 2025, Swissmedic authorised a total of 109 AIs, representing an increase of 56% compared to 2024.[2]

The percentage of accelerated authorisation procedures[3] for AIs was 29% (n=32). The percentage of national accelerated procedures (pooled) increased slightly, from 10% (n=7) to 12% (n=13), with more frequent use of the FTP in particular. Across all applications, the percentage of Orbis applications fell compared to 2024, from 20% to 12% (Type A: n=10, Type B: n=2, Type C: n=1). By contrast, the percentage of Access applications rose from 4% to 7% (n=8).

The percentage of AIs under Art. 13 TPA remained largely unchanged compared to the previous year at 7% (n=8).

Milestone analysis

The percentage of FOs dropped from 36% in 2024 to 30% in 2025. 25% of the applications did not require an LoQ, including 7 under Art. 13 TPA. The percentage of applications without a TRL increased from 80% to 94% compared to the previous year.

Throughput times

In 2025, the national throughput time across all procedures for the 109 AIs was 331 CDs, which is longer by 14 CDs (4%) than in 2024 (317 CDs). The EMA throughput time was 13% longer compared to 2024, at 309 CDs (n=64), whereas the FDA time was 2% shorter, at 183 CDs (n=59).

For AIs (all procedures), the Swissmedic throughput time was 7% longer compared to the EMA (309 CDs) and 81% longer compared to the FDA (183 CDs, Figure 3).

The throughput time of 383 CDs (n=72) for AIs under the standard procedure increased by 10% compared with the previous year (347 CDs, n=43). By contrast, the throughput time for applications under Art. 13 TPA fell by 33% to 181 CDs (n=8).

At 201 CDs, the throughput time for FTP applications (n=7) was particularly short.

Although the throughput time for Orbis A applications (n=10) lengthened by 21%, at 222 CDs these applications continue to be processed very quickly. The throughput time for Access applications remained stable, at 319 CDs (-2%).

Both Swissmedic and companies complied with the time limits for all procedures.

Additional indications: throughput times
All procedures (2022 – 2025)

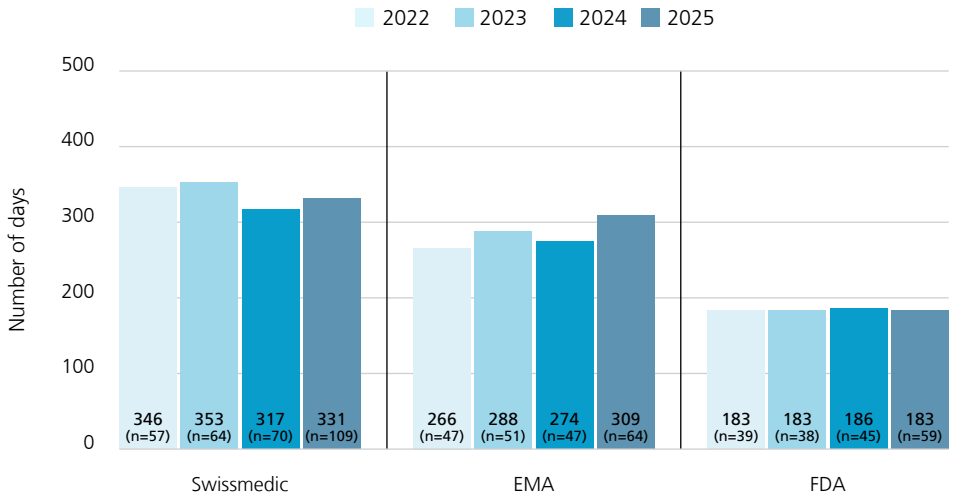

Figure 3: Comparison of throughput times of Swissmedic, the EMA and the FDA for additional indications (all procedures), 2022 – 2025 (median values, n: number of applications). The scope and content of applications for additional indications may vary between Swissmedic, the EMA and the FDA.

Submission and approval gaps

In 2025, data sets for the evaluation of the submission and approval gaps were available for 64 (59%) AIs for the comparison with the EMA and 59 (54%) AIs for the comparison with the FDA.

Compared with the EMA, the submission gap for AIs across all procedures narrowed by 49% compared with the previous year, from 182 CDs to 93 CDs, while the approval gap was 33% narrower, falling from 204 CDs to 137 CDs. The submission gap for applications in the Orbis Type A procedure (n=4) was 5 CDs, and authorisation was granted in Switzerland 18 CDs earlier than in the EU.

Compared with the FDA, the submission gap for AIs across all procedures decreased by 37% compared to the previous year, from 225 CDs to 142 CDs. The approval gap was 304 CDs, 20% smaller than in the previous year (378 CDs, Figure 4). The submission gap compared to the FDA for Type A Orbis applications (n=7) was almost the same as in the previous year, at 30 CDs, while the approval gap widened from 40 CDs to 55 CDs.

Additional indications: submission and approval gaps
All procedures (2023 – 2025)

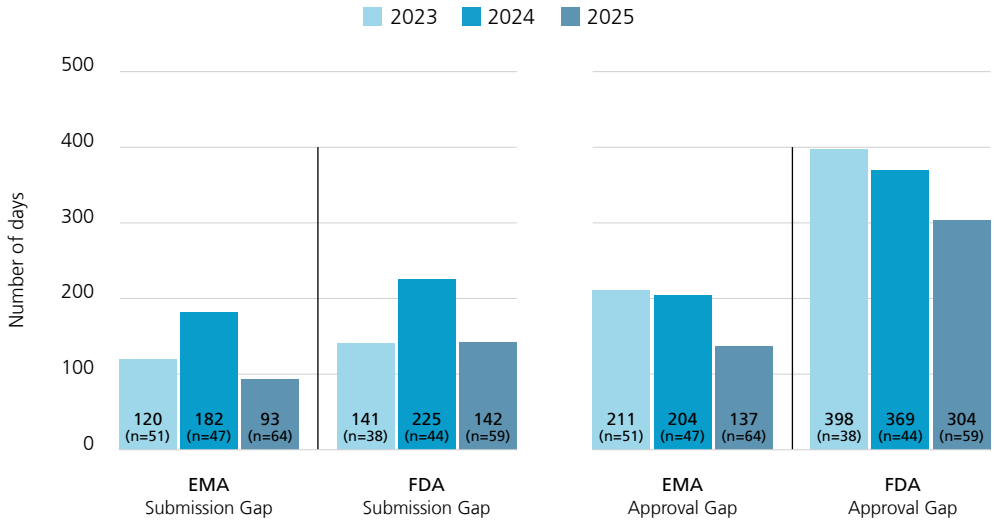

Figure 4: Additional indications (all procedures): median values for the Swissmedic submission and approval gaps compared with the EMA and FDA, 2023 – 2025 (n: number of applications).

Known active substances without innovation (generics) and with innovation

KAS without innovation (generics)

New applications for KAS without innovation can be submitted to Swissmedic two years before document protection for the original preparation expires. The current time limit schedules thus enable decisions on authorisation to be made in good time.

In 2025, Swissmedic authorised a total of 109 KAS without innovation, representing an increase of 20% compared to 2024. An FO was issued in almost half of the applications, reflecting a reduction from 55% in 2024 to 49% in 2025. An LoQ was not required for 29% of the applications, for which Art. 13 TPA was employed in all cases. The percentage of applications without a TRL, at 76%, was identical compared to the previous year.

The throughput time for KAS without innovation under the standard procedure at Swissmedic was 523 CDs (n=51), 2% shorter than in 2024. The procedure under Art. 13 TPA was employed in 50% of cases (n=55), resulting in a throughput time of 349 CDs, a reduction of 174 CDs (-33%) compared with the standard procedure.

KAS with innovation

In 2025, Swissmedic authorised a total of 41 KAS with innovation, representing an increase of 52% compared to 2024. The proportion of FOs rose from 63% in 2024 to a clear majority of 73% in 2025. An LoQ was not required for 17% of the applications, all of which employed a reliance procedure. The percentage of applications without a TRL increased from 41% to 59% compared to the previous year.

The throughput time for KAS with innovation under the standard procedure at Swissmedic was 571 CDs (n=15), 8% shorter than in 2024. The procedure under Art. 13 TPA was used in 29% of cases (n=12), resulting in a throughput time of 476 CDs, a reduction of 95 CDs (-17%) compared with the standard procedure.

As in previous years, the throughput time for applications under Art. 14 para. 1 let. a$^{\text{bis-quater}}$ TPA (n=13) was longer, at 629 CDs, than for those employing the standard procedure.

Other procedures

In 2025, Swissmedic authorised a total of 28 extensions for new dosage forms, representing an increase of 22% compared to 2024. The median throughput time across all procedures was 441 CDs (+7%).

In 2025, Swissmedic authorised a total of 24 biosimilars, representing an increase of 380% compared to 2024. The median throughput time across all procedures was 312 CDs (-26%). Whereas a longer throughput time of 435 CDs was noted for applications under the standard procedure (n=9), applications under Art. 13 TPA (n=13) were processed much faster, at 239 CDs, thanks to the lack of an LoQ.

Herbal medicinal products were not assessed due to the small sample size (n=1).

Strengths and weaknesses of the study

The benchmarking study is the result of regular dialogue between Swissmedic and the industry. Together they identify and discuss current trends, a process that has already yielded a number of process optimisations in the past. The results of the benchmarking study will continue to spark measures to improve authorisation processes for human medicinal products going forward.

Since 2024, the national analyses have included all completed applications with a positive decision, thereby providing a complete picture of the throughput times for human medicinal products in Switzerland.

One limitation of the study in the past was the fact that the international data were provided by the participating applicants, meaning that the available data were incomplete. In the current study, for the first time the international NA NAS data were obtained by Swissmedic from publicly accessible data from the EMA and FDA, allowing a comprehensive analysis of all the applications. The international data for the AIs continue to be supplied by the participating companies. Consequently, since only some of the data were available (EMA: n=64, 59% of the AIs authorised by Swissmedic; FDA: n=59, 54% of the AIs authorised by Swissmedic), a possible selection bias cannot be ruled out.

In addition to the benchmarking study, each year Swissmedic publishes an overview of new authorisations in Switzerland:

- Authorisations of human medicinal products with a new active substance and additional indications 2025[2]

Each year, the Centre for Innovation in Regulatory Science (CIRS), in collaboration with Swissmedic and other leading regulatory authorities, also publishes an R&D Briefing, in which additional key performance indicators for authorisation applications are analysed in an international comparison. With a few exceptions, this Briefing includes all NA NAS authorised in Switzerland:

- R&D Briefing 106: New drug approvals in six major authorities 2016 – 2025: Trends in an evolving regulatory landscape[4]

[4] Lara J, Kermad A, Bujar M, McAuslane N. 2026. R&D Briefing 106: New drug approvals in six major authorities 2016 – 2025: Trends in an evolving regulatory landscape. Centre for Innovation in Regulatory Science. London, UK.