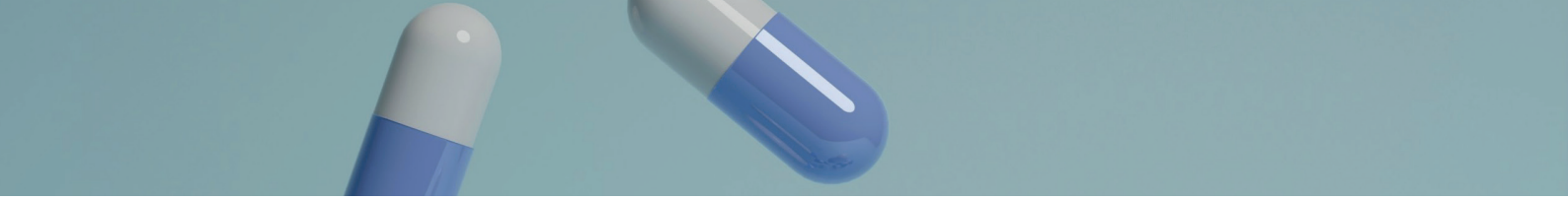
Executive Summary – Benchmarking 2024

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



Abstract

For the twelfth 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 implement improvements in the authorisation processes for human medicinal products.

The analysis is based on new applications for new active substances (NA NAS), additional indications (AIs), extensions and procedures for known active substances (KAS). The analysis of the throughput times in Switzerland considered all completed applications with a positive decision in 2024 (NA NAS: n=46, AIs: n=70, KAS: n=118, extensions: n=23). The data for the Swiss procedures originate directly from Swissmedic and cover 100% of the applications completed in 2024. The applications included in the study for the international comparison of the authorisation times for Swissmedic, the EMA and FDA were obtained directly from the participating companies and comprise 47.9% of the applications submitted to Swissmedic in 2024 (n=127).

Compared with the previous year, throughput times for Swissmedic authorisation procedures followed divergent trends:

Across all procedures, there were no major changes in NA NAS applications compared with the previous year. The only minor change was a longer throughput time for the NA NAS applications in the procedure according to Art. 13 TPA. By contrast, the throughput time for AI applications was 10% shorter compared with 2023.

The EMA was 7% faster than Swissmedic for NA NAS (all procedures) and 16% faster for AI applications (all procedures). The FDA remained significantly faster than Swissmedic: throughput times were 45% shorter for NA NAS (all procedures) and 41% shorter for AIs (all procedures).

Overall, both the submission gap and the approval gap for NA NAS between Swissmedic and the EMA narrowed year-on-year. In the comparison with the FDA, the submission gap was wider and the approval gap narrower compared to 2023. For the AI applications, the submission gap widened against both the EMA and the FDA year-on-year, although the approval gap against both reference authorities was narrower.

As regards known active substances, the throughput times for KAS without innovation (generics) in the standard procedure were slightly longer than in the EU. Throughput times for cases where the procedure under Art. 13 TPA was applied were shortened compared with the standard procedure.

In the labelling phase, the percentage of applications with text review rounds was virtually unchanged, at 29%, compared to the previous year.

Summary of the report

Methods

Benchmarking study inclusion criteria

The benchmarking study included new applications for new active substances (NA NAS), additional indications (AIs), new applications for known active substances with or without innovation (NA KAS with/without innovation), new applications for biosimilars, new applications for herbal medicinal products under the simplified procedure (NA herbal medicinal products) and extensions that were authorised for the Swiss market in 2024.

Procedure

Swissmedic forwarded the raw data for all applications that qualified for inclusion to the market research agency intervista[1]. The participating companies also supplied the EMA and FDA data for the applications in question to intervista, which then analysed the data. The data were only evaluated if at least two NA NAS applications or at least five AI applications satisfied the specified criteria.

Notes on how the submission and approval gaps were calculated

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. In the case of NA NAS and AIs, the median of the two values is shown for international evaluations.

New applications for new active substances (NA NAS)

Authorisation procedures

Swissmedic authorised a total of 46 NA NAS applications in 2024[2]. 41% (n=19) of the 46 NA NAS applications in 2024 were processed in an accelerated authorisation procedure.[3]

The proportion of Orbis and Access applications (pooled) was identical to the previous year, at 17% (n=8). Access (n=5) procedures were used slightly more frequently than Orbis ones (Type A: n=2; Type C: n=1).

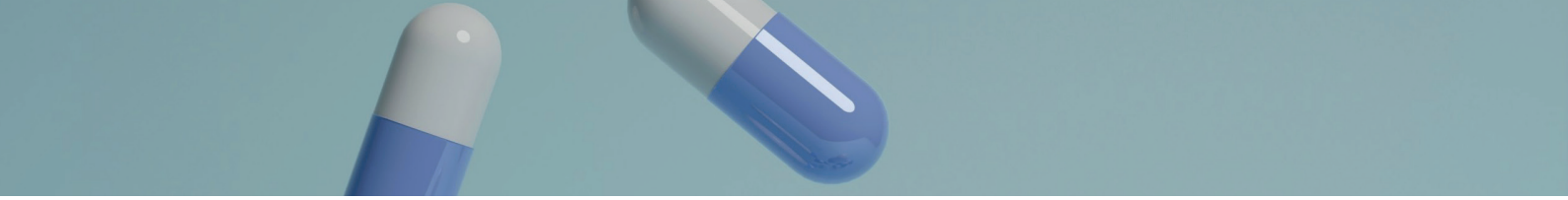
Throughput times

In 2024, the median national throughput time across all procedures for the 46 NA NAS was 445 calendar days (CDs), and therefore comparable with 2023 (442 CDs). Internationally, the median Swiss

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

[2] Authorisations of human medicinal products with a new active substance and additional indications 2024 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.



throughput time was 8% longer than the EMA (413 CDs) and 82% longer than the FDA (245 CDs, Figure 1). Swissmedic's throughput time for NA NAS submitted to all three authorities (n=14) was 332 CDs, 18% shorter than the previous year's figure of 403 CDs (n=21). The Swissmedic throughput times for these applications was 19% faster than the EMA and 14% slower than the FDA.

Year-on-year the following developments were observed in respect of throughput times:

The throughput times for NA NAS under the standard procedure remained almost identical compared to 2023 (n=16, 519 CDs, + 2%; those with orphan drug status: n=6, 530 CDs, -2%). The throughput times for FTPs (n=4, 278 CDs, -1%) and temporary procedures (n=5, 225 CDs, -2%) were comparable with those in the previous year. The applications in Orbis Type A procedures took longer to process (n=2, 316 CDs, +7%), while the throughput time was shorter in Access procedures compared to 2023 (n=5, 329 CDs, -7%).

The throughput time for NA NAS under Art. 13 TPA was longer than in 2023 (n=13, 389 CDs, +41%). This also applies to the proportion of NA NAS under Art. 13 TPA with orphan drug status (n=10, 333 CDs, +30%).

New applications for new active substances: throughput times
All procedures (2021 – 2024)

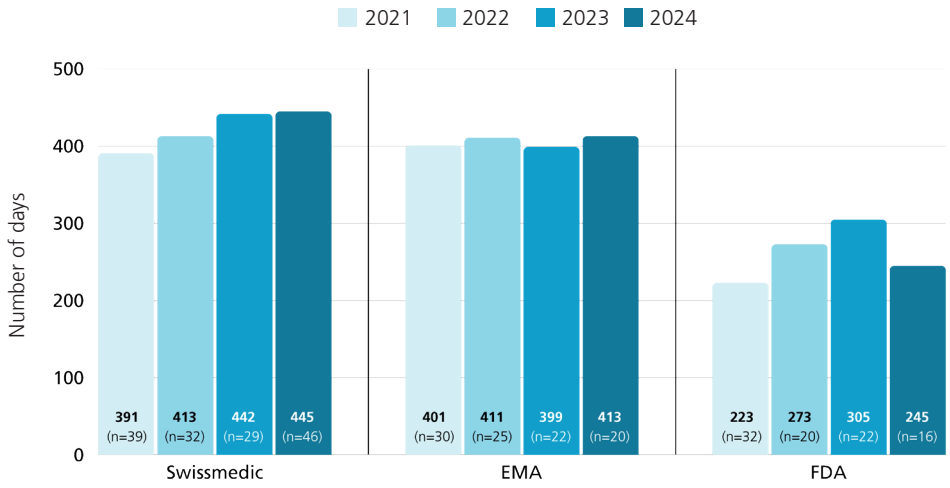


Figure 1: Comparison of throughput times of Swissmedic, the EMA and the FDA for new applications for new active substances (NA NAS) across all procedures, 2021-2024 (median values, n: number of applications).

Submission and approval gaps

In 2024, data for the submission and approval gaps compared with the EMA were available for a total of 20 of the 46 NA NAS applications across all procedures. Compared with the FDA, data were available for 15 of the 46 NA NAS applications across all procedures.

Compared with the EMA, the submission and approval gaps for NA NAS applications across all procedures narrowed in 2024 compared to the previous year. The submission gap was 225 CDs, 8% lower than in 2023. At 219 CDs, the approval gap was also lower (-12%, see Figure 2). The submission gap for NA NAS applications under the standard procedure (n=5) rose by 93% to 247 CDs, while the approval gap increased by 14% to 264 CDs.

Compared with the FDA, the submission gap for NA NAS applications across all procedures rose by 20% compared with the previous year from 270 to 323 CDs, but the approval gap shrank by 9%, from 369 to 335 CDs. The submission gap for NA NAS applications under the standard procedure (n=2) shrank by 18% to 295 CDs, while the approval gap narrowed by 52% to 182 CDs.

New applications for new active substances: submission gap and approval gap
All procedures (2022 – 2024)

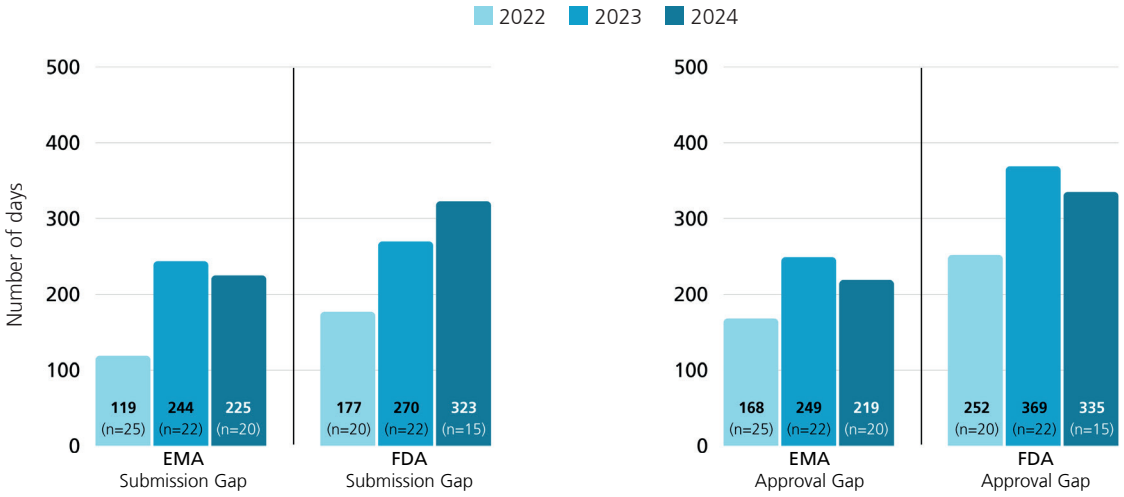
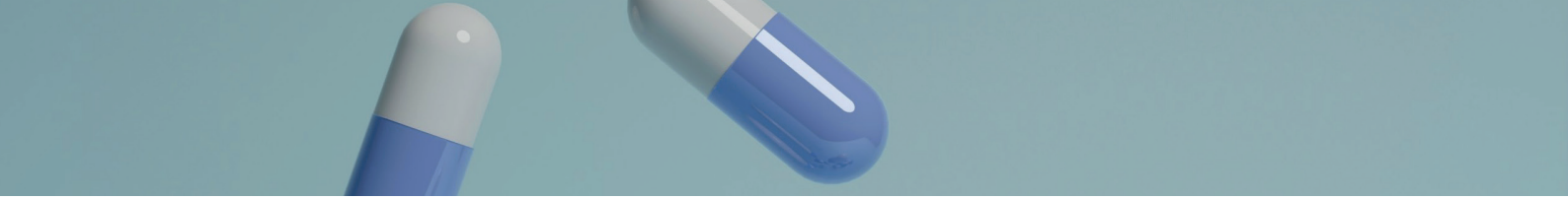


Figure 2: NA NAS (all procedures): median values for the Swissmedic submission and approval gaps compared with the EMA and FDA[4], 2022-2024 (n: number of applications).

[4] Since median times have been used, the approval gap does not exactly match the total of submission gap and difference in throughput time.



Additional indications (AIs)

Authorisation procedures

In 2024, Swissmedic authorised a total of 70 additional indications (AIs)[2]. The percentage of fast-track authorisation procedures[5] for AIs was 33% (n=23). The percentage of Orbis and Access applications (pooled) was 24% (n=17). As regards international procedures, the Orbis procedure was used particularly often for AIs (Type A: n=7, Type B: n=2, Type C: n=5). Three AIs were authorised under the Access procedure.

Throughput times

The median assessment times for AIs across all procedures (n=70) in Switzerland, at 317 CDs, were shorter by 36 CDs compared with 2023 (-10%).

Compared with Swiss authorisation times, the EMA was 14% faster, with a median time of 274 CDs (n=47), while the FDA was 41% faster with a median time of 186 CDs (n=45; Figure 3). The median throughput time of 347 CDs (n=43) for AIs under the standard procedure changed very little compared with the previous year (359 CDs, n=54). Both Swissmedic and the industry complied with median time limits, both overall and in the various application phases.

Additional indications: throughput times
All procedures (2021 – 2024)

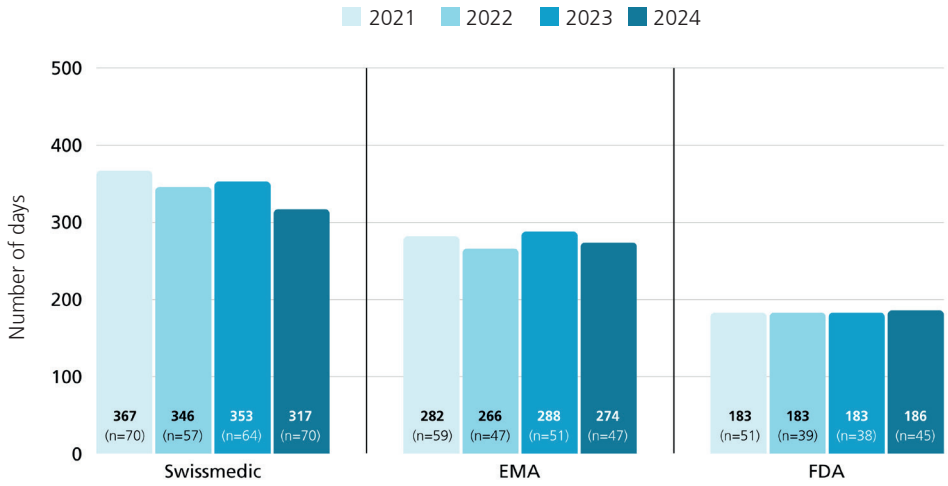


Figure 3: Comparison of throughput times of Swissmedic, the EMA and the FDA for additional indications (all procedures), 2021-2024 (median values, n: number of applications). The scope and content of applications for additional indications may vary between CH, EU and USA.

[5] Temporary authorisation, fast-track authorisation procedure, procedure with prior notification and the international procedures Access and Orbis

Submission and approval gaps

In 2024, reference submission and authorisation data from the EMA were available for 47 of the 70 AI applications and from the FDA for 44 applications.

Compared with the EMA, the submission gap for AIs across all procedures (n=47) widened by 52% to 182 CDs. The approval gap was 204 CDs, 3% lower than in 2023 (Figure 4). By contrast, a submission gap of 22 CDs was observed for applications in the Orbis Type A procedure, and approval was granted in Switzerland after a median of 71 CDs earlier than in the EU.

Compared with the FDA (n=45), the submission gap across all procedures widened by 60% to 225 CDs. The approval gap was 378 CDs, 5% lower than in 2023 (Figure 4). The submission gap compared to the FDA for Type A Orbis applications (n=6) was the same as in the previous year, at 29 CDs, while the approval gap decreased from 173 CDs to 40 CDs (-77%).

Additional indications: submission gap and approval gap
All procedures (2022 – 2024)

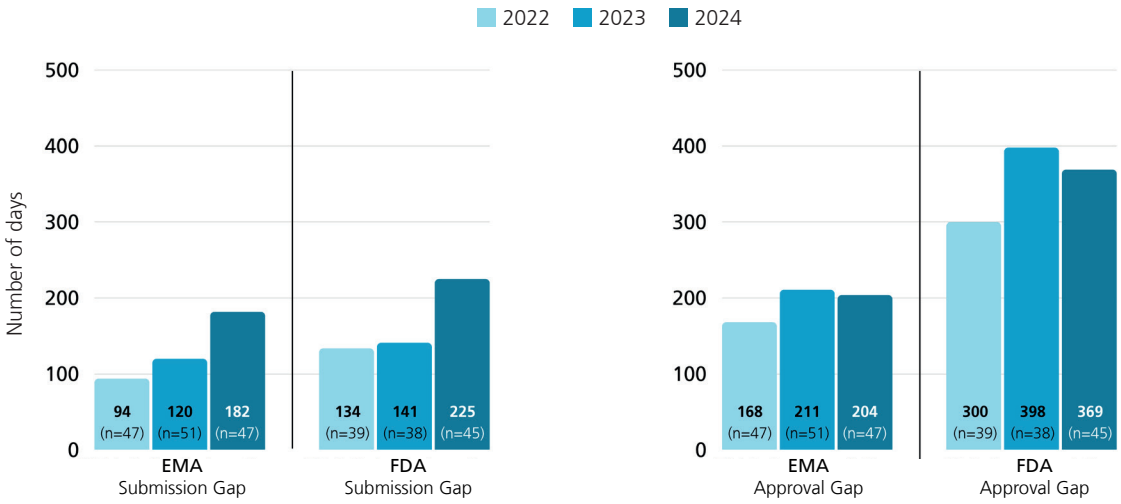
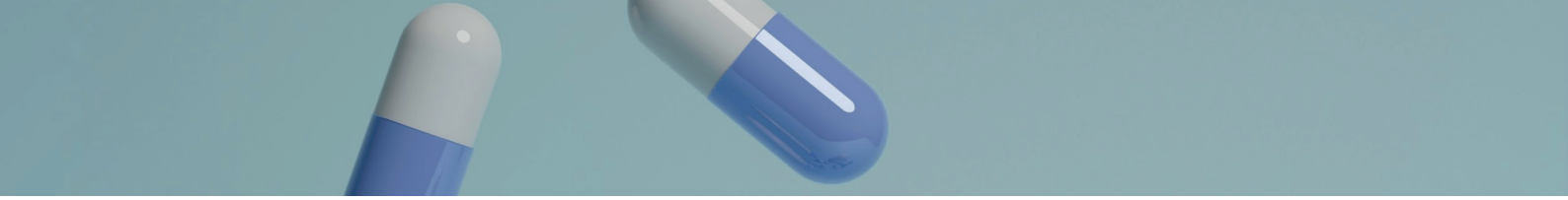


Figure 4: Additional indications (all procedures): median values for the Swissmedic submission and approval gaps compared with the EMA and FDA[6], 2022-2024 (n: number of applications).

[6] Since median times have been used, the approval gap does not exactly match the sum of the submission gap plus the difference in throughput time.



Text review rounds

Once the scientific assessment has been completed, additional text review rounds during the labelling phase may result in significant delays to marketing authorisation. This application phase is evaluated separately in this study for this reason.

Overall, additional text review rounds were carried out in 2024 for 29% of all applications (NA NAS, AIs, KAS with/without innovation, biosimilars, herbal medicinal products, extensions). The percentage of applications with additional text review rounds for NA NAS was 37%, compared to 20% for AIs, 59% for KAS with innovation and 24% for KAS without innovation.

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 2024, Swissmedic authorised 91 KAS without innovation. The median throughput time for KAS without innovation in the standard procedure at Swissmedic was 532 CDs (n=52) or 4% longer than at the EMA (512 CDs, n=22).[7] The procedure under Art. 13 TPA was used in 40% of cases (n=37) involving KAS without innovation, resulting in a median throughput time of 315 CDs (2023: 337 CDs) and a time gain of 217 CDs or 41% compared with the standard procedures.

KAS with innovation

In 2024, a total of 27 KAS with innovation were authorised by Swissmedic. The throughput times for KAS with innovation in the standard procedure (n=8) were 26% longer than the previous year, at 619 CDs. Compared with the EMA's 411 CDs, Swissmedic's throughput time for the standard procedure was 51% longer.[8] The procedure under Art. 13 TPA was applied in 52% (n=14) of applications for KAS with innovation; the median throughput time of 424 CDs (2023: 428 CDs) was 31% shorter than for the standard procedure.

Insufficient meaningful results are available in this year's study for assessing applications under Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA.

[7] Reference data for the FDA not available for 2024 (n=2). The FDA throughput time in 2022 was 1971 CDs (n=7).
[8] Reference data for the FDA not available for 2024 (n=1). The FDA throughput time in 2021 was 461 CDs.

Other procedures

A total of 23 extensions for new dosage forms were approved in 2024. The median throughput time across all procedures was 414 CDs.

As a result of the small number of applications, meaningful data for biosimilars and herbal medicinal products are insufficient in this year's study for an assessment.

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.

One limitation of the study in previous years is the fact that the applications analysed did not cover 100% of all the applications that were actually completed. For the first time, all the applications submitted to Swissmedic could be included in this study. Consequently, the figures for previous years are less meaningful in individual assessments than the complete data collected for 2024. Any numerical trends may therefore be attributable to the changed methodology.

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 2024[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 101: New drug approvals in six major authorities 2015-2024: Trends in an evolving regulatory landscape[9]

[9] Lara J, Kermad A, Bujar M, McAuslane N. 2025. *R&D Briefing 101: New drug approvals in six major authorities 2015-2024: Trends in an evolving regulatory landscape*. Centre for Innovation in Regulatory Science. London, UK.