Executive Summary – Benchmarking 2023

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

Abstract

For the eleventh 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 (AI) and procedures for known active substances (KAS). The applications submitted for the study by participating authorisation holders account for 78.9% of the total Swiss market and 83.9% of the market for prescription-only medicinal products.

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

The study identified rising throughput times (+15%) for NA NAS in the standard procedure, the effect being particularly pronounced (+72%) in the orphan drugs subgroup owing to a high level of text review rounds. There were no material changes observed in AI applications.

Throughput times for NA NAS under the Type A Orbis procedure and under Art. 13 TPA were substantially (28% and 24% respectively) shorter than in the previous year.

Swissmedic was 11% slower than the EMA on NA NAS (all procedures) and 19% slower on AI applications (all procedures). The FDA remained substantially faster than Swissmedic, with throughput times that were 31% shorter for NA NAS (all procedures) and 48% shorter for AIs (all procedures).

Overall, both the submission gap and the approval gap widened year-on-year against the reference authorities EMA and FDA. The exceptions to this were NA NAS under the standard procedure, where the submission and approval gaps were shorter than the previous year compared with both the EMA and FDA.

Turning to KAS, throughput times for KAS without innovation (generics) under the standard procedure are 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 increased overall from 20% to 28%. The increase was most pronounced among KAS (from 14% to 25%).

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 and new applications for herbal medicinal products under the simplified procedure (NA herbal medicinal products) that were authorised for the Swiss market in 2023. Data was only used after applicants had provided a declaration of authorisation.

Procedure

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

The international analysis compares Swissmedic's overall throughput times with those of the EMA and FDA. In 2023, applications under Swissmedic's standard procedure were generally compared with applications under the EMA's or FDA's standard procedure, while applications under the fast-track authorisation procedure were compared with applications undergoing a fast-track procedure with the EMA (accelerated assessment) or FDA (Priority Review) wherever possible (exceptions are identified in the report). The national benchmarking exercise analyses the individual phases of Swissmedic applications (with the exception of rolling procedures conducted with partner authorities in other countries), the various procedure types and total throughput times. The complete evaluations from the data analysis are not publicly accessible. This Executive Summary, which has been compiled by Swissmedic and the participating industry associations, sets out the key results.

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.

[1] Polyquest – Market research and usability

New applications for new active substances (NA NAS)

Authorisation procedures

Swissmedic authorised a total of 41 NA NAS in 2023[2], 29 (71%) of which are included in this benchmarking study. All the figures below relate exclusively to the 29 applications included in this analysis.

Fast-track authorisation procedures (fast-track authorisation procedures (FTPs) and procedures with prior notification (PPNs) pooled) accounted for 14% (n=4) of NA NAS, approximately the same proportion as in 2022 (16%; n=5), although the applications analysed in 2023 did not include any PPNs. Three (previous year: six) applications were completed under the fast-track temporary authorisation procedure.

There were no significant year-on-year changes in the number of Type A Orbis (n=3) and Access (n=4) applications.

Throughput times

In 2023, the median national throughput time across all procedures for the 29 NA NAS analysed was 442 calendar days (CDs), 7% higher than in 2022 (413 CDs). Internationally, the median Swiss throughput time was 11% longer than the EMA (399 CDs) and 45% longer than the FDA (305 CDs, figure 1).

Swissmedic's throughput time for NA NAS submitted to all three authorities (n=21) was 403 CDs, which is in a similar range to the previous year's figure of 419 CDs. Throughput times for FTPs declined (n=4, 280 CDs, -16%), as did Type A Orbis applications (n=3, 295 CDs, -28%) and NA NAS under Art. 13 TPA (n=5, 276 CDs, -24%).

However, throughput times for NA NAS under the standard procedure increased (n=19, 465 CDs, +15%), particularly for NA NAS with orphan drug status under the standard procedure (n=9, 541 CDs, +72%). Overall, however, the total throughput time for NA NAS under the standard procedure was within the specified time limit (480 CDs). Furthermore, both Swissmedic and the industry complied with median timelines within the different application phases.

Moreover, throughput times for NA NAS under the temporary authorisation procedure (n=3, 230 CDs, +9%) and the Access procedure (n=4, 352 CDs, +4%) were broadly the same.

[2] Authorisations of human medicinal products with a new active substance and additional indications 2023. Swissmedic, Bern, CH.

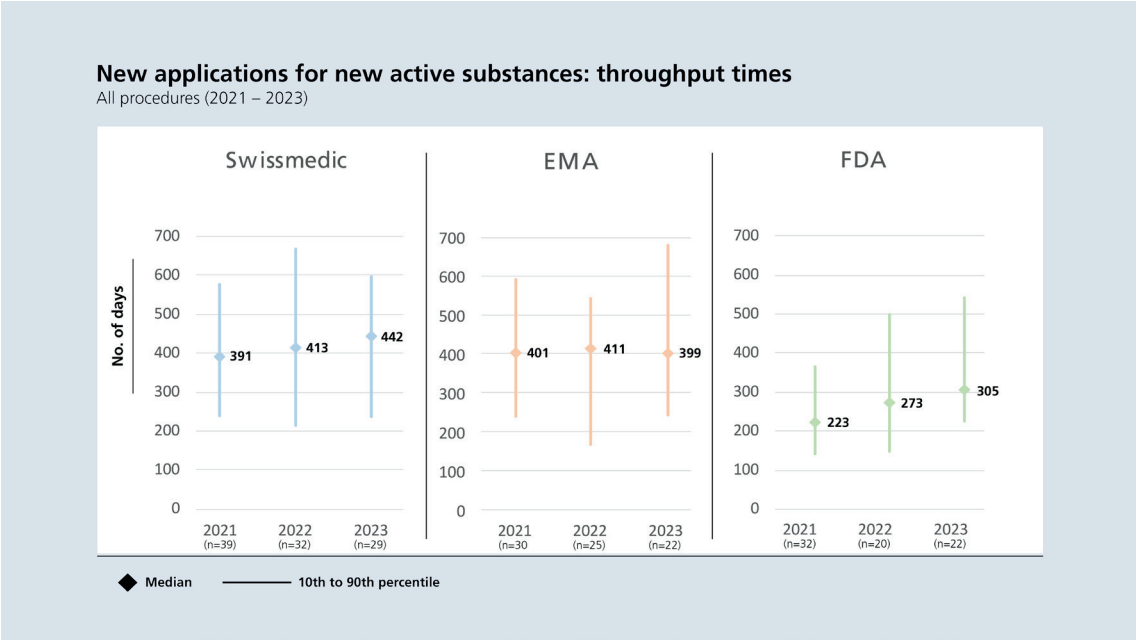

Figure 1: Comparison of throughput times of Swissmedic, the EMA and the FDA for new applications for new active substances (NA NAS) across all procedures, 2021-2023 (median values with 10th and 90th percentiles).

Submission and approval gaps

The submission gap indicates the difference between submission to the EMA and FDA and submission to Swissmedic; the approval gap the difference between authorisation by the EMA and FDA and authorisation by Swissmedic. In 2023, submission and approval gap data was available for 22 of the 29 NA NAS.

The submission and approval gaps between Swissmedic and the EMA widened year-on-year. The submission gap was 244 CDs, 105% higher than in 2022. At 249 CDs, the approval gap was also higher (+48%, see figure 2).

The submission gap for NA NAS under the standard procedure (n=16) fell by 40% to 128 CDs, while the approval gap narrowed by 14% to 232 CDs.

Compared with the FDA, the submission gap for NA NAS across all procedures rose 53% compared with the previous year from 177 to 270 CDs. The approval gap also increased 46% from 252 to 369 CDs.

Compared with the FDA, the submission gap for NA NAS under the standard procedure (n=7) shrank by 31% to 360 CDs, while the approval gap narrowed by 58% to 376 CDs.

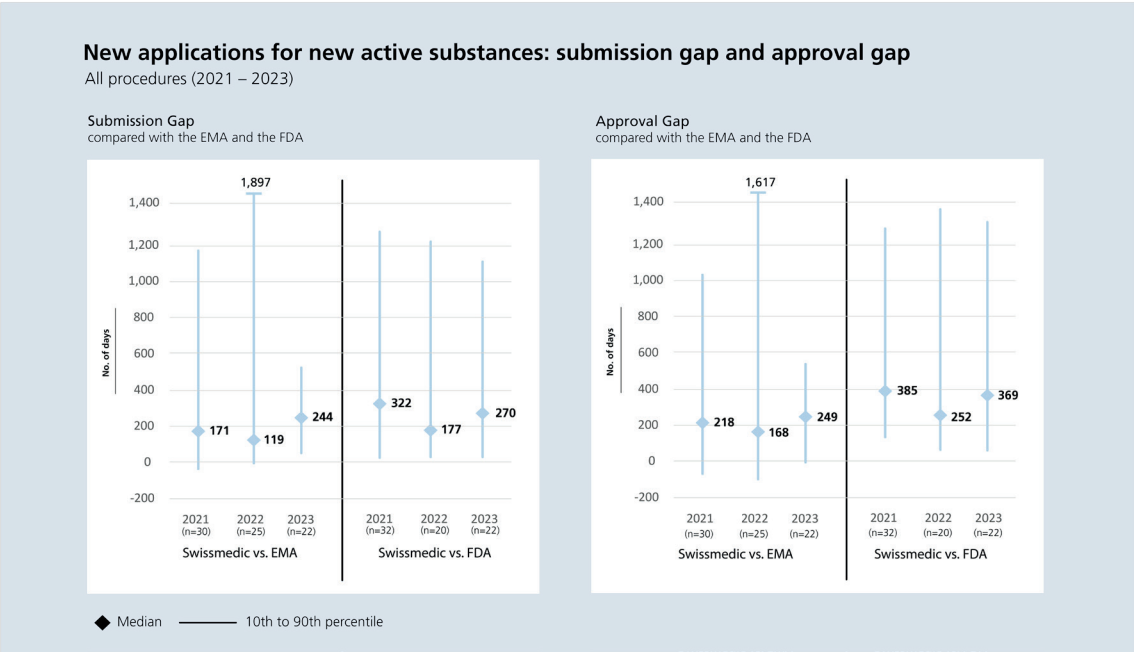

Figure 2: NA NAS (all procedures): submission gap and approval gap[3] in Switzerland compared with the EMA and FDA, 2021–2023 (median values with 10th and 90th percentiles).

Additional indications (AIs)

Authorisation procedures

In 2023, Swissmedic authorised a total of 65 additional indications (AIs)[2]. 64 (98%) of these were included in the study. All the figures below relate exclusively to the 64 applications included in this analysis.

At 5% (n=3), the percentage of fast-track authorisation procedures (FTPs and PPNs pooled) for AIs declined compared to the previous year (11%, n=6).

By contrast, the percentage of Orbis and Access applications (pooled) was unchanged on 2022 at 16% (n=10; previous year: 16%, n=9). As regards international procedures, the Orbis procedure was used particularly often for AIs (Type A: n=7, Type B: n=1, Type C: n=1). One AI was authorised under the Access procedure.

Throughput times

The median assessment times across all procedures (n=64) in Switzerland changed only minimally compared with 2022 (353 CDs, +2%; see figure 3).

Compared with Swiss authorisation times, the EMA was 18% faster, with a median time of 288 CDs (n=51), while the FDA was 48% faster with a median time of 183 CDs (n=38; figure 3).

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

The median throughput time for AIs under the standard procedure was 359 CDs (n=54). Again, this is virtually unchanged on the previous year's figure of 355 CDs (n=49). Both Swissmedic and the industry complied with median time limits, both overall and in the various application phases.

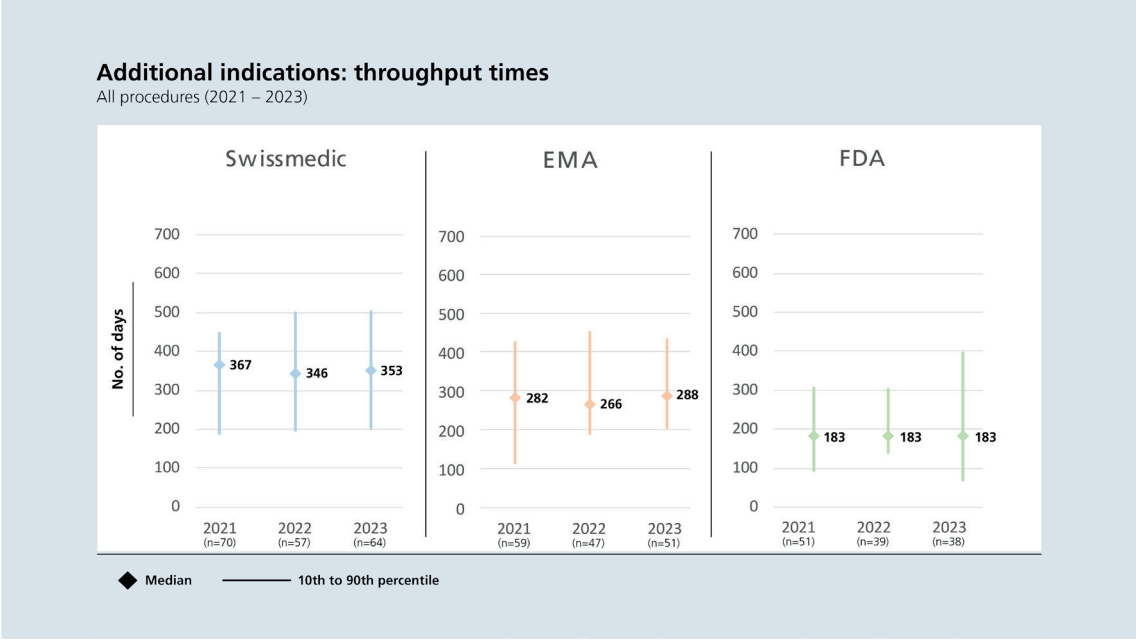

Figure 3: Comparison of throughput times of Swissmedic, the EMA and the FDA for additional indications (all procedures), 2021-2023 (median values with 10th and 90th percentiles). The scope and content of applications for additional indications may vary between CH, the EU and the USA.

Submission and approval gaps

In 2023, reference submission and authorisation data from the EMA was available for 51 of the 64 AI applications and from the FDA for 38 applications.

Compared with the EMA, the submission gap for AIs across all procedures (n=51) widened by 28% to 120 CDs. The approval gap was also 26% higher than in 2022, at 211 CDs. By contrast, the submission gap for Type A Orbis applications narrowed by 39% to 14 CDs, while the approval gap shrank by an even greater margin of 57% to 15 CDs.

Compared with the FDA (n=38), the submission gap across all procedures widened by 5% to 141 CDs. The approval gap increased by 33% year-on-year to 398 CDs. The submission gap for Type A Orbis applications (n=7) was 16% higher at 29 CDs, while the approval gap rose from 18 to 173 CDs (867%).

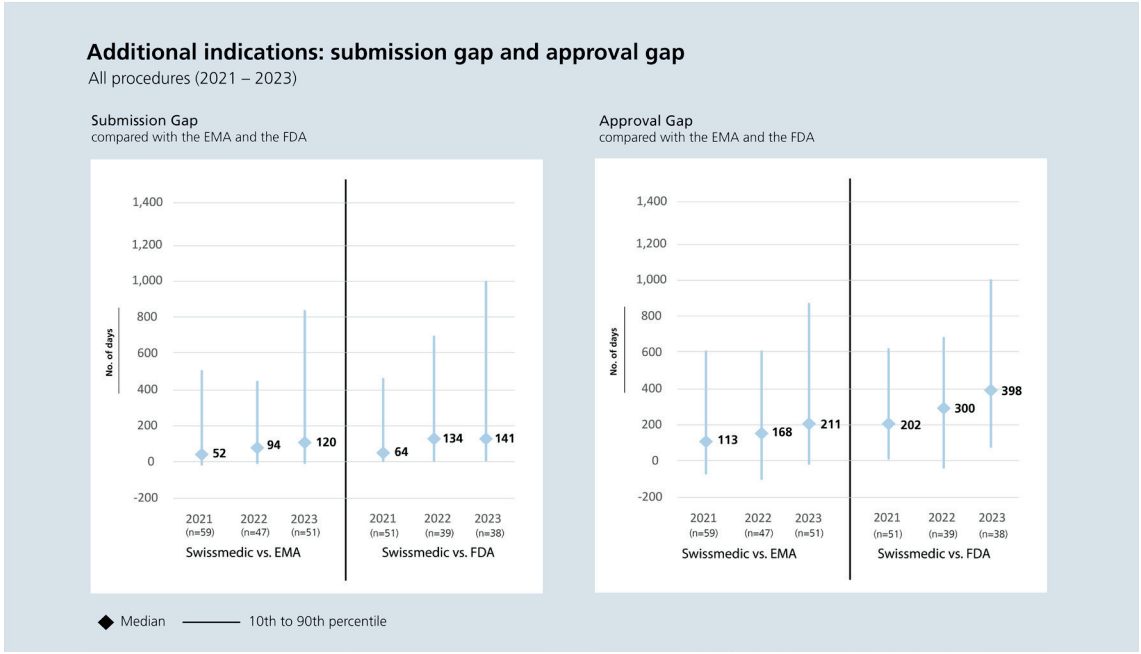

Figure 4: Additional indications (all procedures): submission gap and approval gap[3] in Switzerland compared with the EMA and FDA (median values with 10th and 90th percentiles).

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 for this reason.

For all procedures, the percentage of applications with text review rounds increased from 20% to 28% – from 37% to 48% for NA NAS, from 18% to 25% for AIs and from 14% to 25% for KAS.

Known active substances without innovation (generics)/with innovation and biosimilars

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 2023, Swissmedic authorised 102 KAS without innovation. 83 (81%) of these applications were included in the study and are factored into the figures below.

The median throughput time for KAS without innovation in the standard procedure at Swissmedic was 506 CDs (n=46) or 9% longer than at the EMA (464 CDs, n=38).[4] The procedure under Art. 13 TPA was used in 41% of cases (n=34) involving KAS without innovation, resulting in a time gain of 169 CDs or 33% compared with the standard procedures. 4% of cases (n=3) were processed under Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA with a throughput time of 512 CDs.

KAS with innovation

Of the 30 applications for KAS with innovation authorised by Swissmedic in 2023, 17 (57%) were included in the study. The figures below relate exclusively to these applications.

The throughput times for KAS with innovation in the standard procedure (n=7) were 5% shorter than the previous year, at 490 CDs. Compared with the EMA's 417 CDs, Swissmedic's throughput time for the standard procedure was 18% longer.[5] The procedure under Art. 13 TPA was applied in 35% (n=6) applications for KAS with innovation; the median throughput time of 428 CDs was 13% shorter than for the standard procedure. 24% of applications (n=4) were assessed under Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA. At 610 CDs, the throughput time was 20% higher than in 2022 (509 CDs).

Biosimilars

No meaningful data on biosimilars was recorded for this year's study, since it was impossible to include sufficient applications.

Other procedures

At 536 CDs, the throughput times for herbal medicinal products (n=2) were 17% higher than in 2022 (459 CDs, n=3).

[4] Reference data for the FDA for 2023 unavailable (n=1). The FDA throughput time in 2022 was 1971 CDs (n=7).
[5] Reference data for the FDA unavailable for 2022/23. The FDA throughput time in 2021 was 461 CDs.

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 restricting factor is that the applications analysed do not cover 100% of the applications that were actually completed in 2023. For this reason, we refer the reader to two additional publications that may contain results that diverge from the benchmarking study because they are based on different data:

- **Overview of new authorisations by Swissmedic 2023**
  The overview of newly authorised human medicinal products[2] published annually by Swissmedic covers 100% of authorised NA NAS and AIs.

- **R&D Briefing des CIRS**
  The annual international R&D Briefing produced annually in conjunction with the Centre for Innovation in Regulatory Science (CIRS)[6] covers all authorised NA NAS with just a few exceptions.

[6] Centre for Innovation in Regulatory Science (2024). R&D Briefing 93: New drug approvals in six major authorities 2014–2023: Changing regulatory landscape and facilitated regulatory pathways. Centre for Innovation in Regulatory Science (CIRS), London, UK.