Executive Summary – Benchmarking 2022

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

Abstract

Swissmedic and the pharmaceutical companies have conducted their 10th benchmarking study of authorisation throughput times for human medicinal products. The applications submitted for the study by participating authorisation holders account for 83% of the total Swiss market and 86% of the market for prescription-only medicinal products.

Over the last ten years, the benchmarking study has provided a valuable basis for dialogue between Swissmedic and the industry. Trends have been recognised and numerous processes have been optimised.

Although analysis of throughput times for new applications for new active substances (NA NAS) across all procedures reveals a slightly longer lead time, Swissmedic's median figures are on a par with the EMA's. The longer delay compared with 2021 is primarily attributable to those applications that were submitted and processed during the intensive pandemic years 2020/2021 and completed in 2022. During that time, applications for medicinal products to combat or prevent COVID were prioritised at the expense of other innovative new applications. Benchmarking shows that the FDA remains significantly faster than Swissmedic and the EMA. In certain categories, such as orphan drugs, throughput times were shorter.

The submission gap[1] and approval gap[2] for NA NAS declined overall compared with the EMA and the FDA, primarily due to the international procedures used by the Access Consortium and Project Orbis as well as the increase in temporary authorisations. It can be assumed that international procedures will continue to grow in importance.

Throughput times for additional indications (AI) were still longer at Swissmedic than at the EMA or FDA, even though Swissmedic has closed the gap with the EMA slightly as the years have progressed. The submission and approval gaps between Swissmedic and the EMA and the FDA were bigger for AI in 2022 than in 2021.

To ensure Swissmedic and the industry can jointly analyse such effects and identify possible measures, dialogue and refinement of authorisation processes will remain important for both going forward.

[1] The submission gap is defined as the time (median) between the date of submission to the reference authority and the date of submission to Swissmedic.

[2] The approval gap is defined as the time (median) between the date of approval by the reference authority and the date of approval by Swissmedic.

Summary of the report in greater detail

New applications for new active substances (NAS)

Authorisation procedures

At 16% (n=5) of NA NAS, the percentage of fast-track authorisation procedures (FTPs and PPNs pooled) was higher than in the previous year (10%; n=4). At 38% (n=12), the percentage of temporary authorisations issued for medicinal products was also higher than in the previous year (23%, n=9). Of those, six applications (previous year: four) were submitted for temporary authorisation and thus benefited from the shorter timeframe.

By contrast, the percentage of Orbis and Access applications (pooled) was virtually unchanged from 2021, at 22% (n=7; previous year 26%, n=10).

Throughput times

In 2022, Swissmedic's median throughput time for NA NAS across all procedures was 413 calendar days (CD), which was virtually the same as the EMA's figure of 411 CD. The FDA's median throughput time was 273 CDs (Figure 1).

There was a significant improvement in median throughput time for NA NAS in the standard procedure with orphan drug status (2022: 315 CD vs 2021: 394 CD, -20%). Median authorisation time for NA NAS in Access Consortium procedures also fell year-on-year (2022: 338 CD vs 2021: 382 CD, -12%).

Compared with 2021, an increase in median throughput time for fast-track and simplified procedures (Orbis Type A, fast-track authorisation, PPN, Art. 13 TPA) was observed. Swissmedic attributes these delays to the increased strain on resources during the COVID pandemic in 2020/21, when applications for medicinal products to combat or prevent the pandemic were given priority over other innovative new applications.

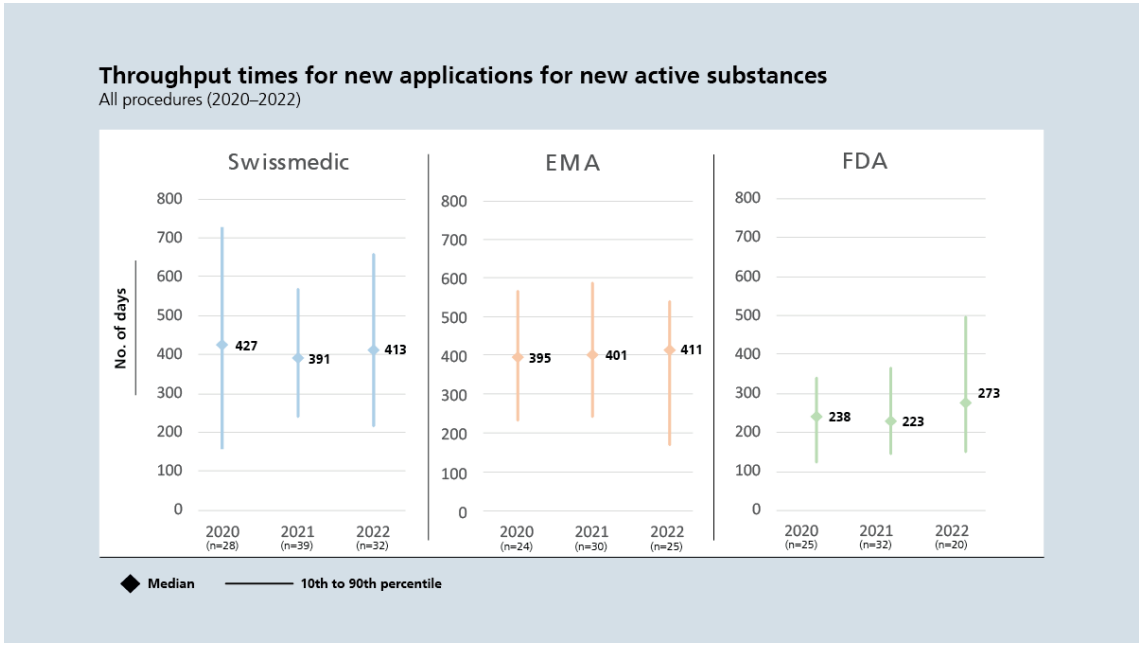

Figure 1: Comparison of throughput times of Swissmedic, the EMA and the FDA for new applications for new active substances (NA NAS) across all procedures, 2020-2022 (median values with 10th and 90th percentiles).

Submission and approval gaps

Year-on-year, the submission gap for NA NAS (all procedures) narrowed by 30% compared with the EMA, from 171 CD to 119 CD, and by 45% compared with the FDA, from 322 CD to 177 CD (Figure 2). This closing of the submission gap was primarily due to the international procedures used in Project Orbis and Access and to temporary authorisations. The submission gap for NA NAS in the standard procedure widened by 13% year-on-year compared with the EMA, from 190 CD to 215 CD, and by 18% compared with the FDA, from 445 CD to 524 CD.

The approval gaps for NA NAS (all procedures) narrowed by 23% compared with the EMA, from 218 CD to 168 CD, and by 35% compared with the FDA, from 385 CD to 252 CD, for the same reasons as the submission gap (Figure 2). The approval gap for NA NAS in the standard procedure widened by 6% year-on-year compared with the EMA, from 254 CD to 270 CD, and by 43% compared with the FDA, from 625 CD to 895 CD.

Despite the progress achieved on the submission and approval gaps, both increased compared with the FDA for NA NAS in the standard procedure sub-group (524 CD, +18% for submission gap; 895 CD, +43% for approval gap). The benchmarking study only started recording the submission and approval gaps in 2021, but will continue to monitor it and track the trend over the next few years.

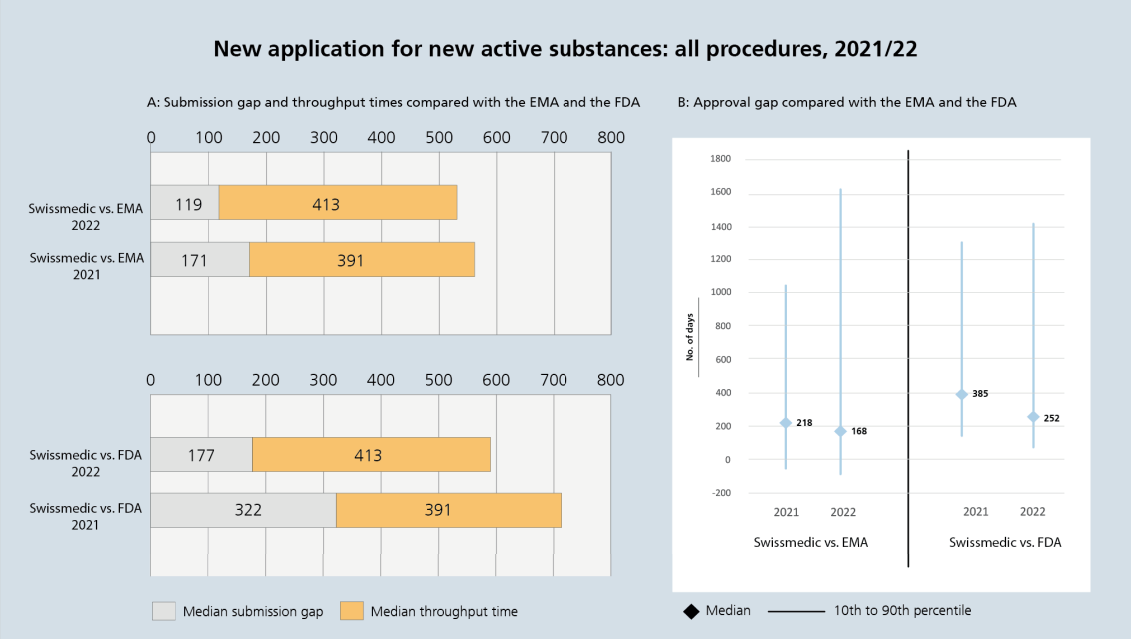

Figure 2: NA NAS (all procedures) submission gap (A) and approval gap (B) in Switzerland compared with the EMA and the FDA[3].

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

Additional indications (AI)

Authorisation procedures

At 11% (n=6), the percentage of fast-track authorisation procedures (FTPs and PPNs pooled) for AI applications was similar to the previous year (13%, n=9). By contrast, the percentage of Orbis and Access applications (pooled) was higher than in 2021, at 16% (n=9; previous year: 10%, n=7).

Throughput times

Assessment times for additional indications in Switzerland fell from 367 CD in 2021 to 346 CD in 2022, a reduction of 6%. Despite this, they are still longer than at the EMA (266 CD, -23%) and the FDA (183 CD, -47%), even though the difference has trended downwards slightly in recent years (Figure 3).

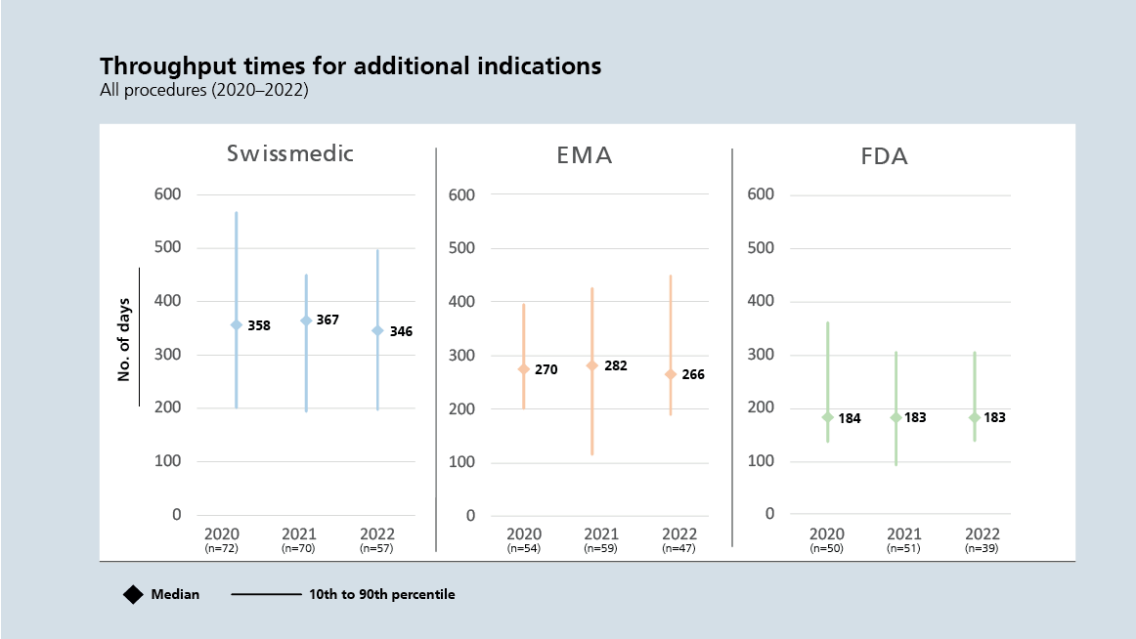

Figure 3: Comparison of throughput times of Swissmedic, the EMA and the FDA for additional indications (all procedures), 2020-2022 (median values with 10th and 90th percentiles). The scope and content of applications for additional indications may vary between CH, EU and USA.

Submission and approval gaps

The submission gap for AI (all procedures) increased 81% year-on-year compared with the EMA, from 52 CD to 94 CD, and by 109% compared with the FDA, from 64 CD to 134 CD. (Figure 4).

The approval gaps also grew correspondingly, from 113 CD to 168 CD (+48%) compared with the EMA and from 202 CD to 300 CD compared with the FDA (+49%).

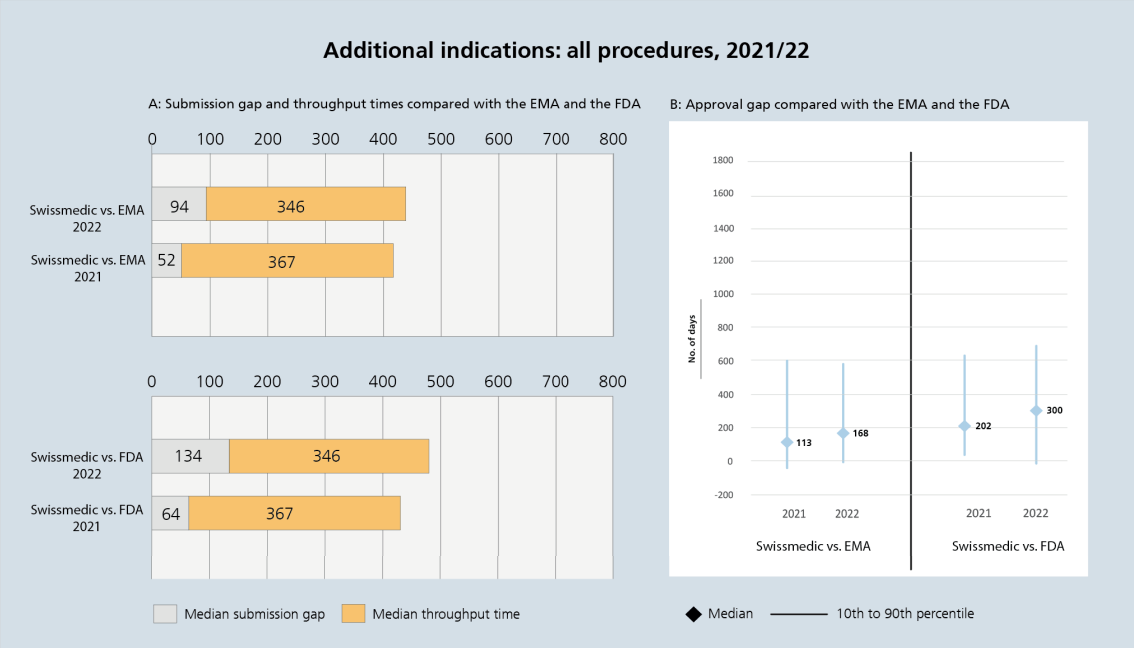

Figure 4: Indication extensions (all procedures): submission gap (left) and approval gap (right) in Switzerland compared with the EMA and the FDA[4].

Text correction rounds

Once the scientific assessment has been completed, additional text correction rounds during the labelling phase may result in significant delays to marketing authorisation. This has prompted Swissmedic to review the effectiveness of the measures it has adopted. The percentage of applications involving text correction rounds increased marginally across all types (NA NAS, biosimilars, AI, KAS with/without innovation) from 19% to 20%.

The percentage of NA NAS applications involving text correction rounds increased from 28% to 37%, while the equivalent figure for AI fell from 21% to 18%. It was also found that where NA NAS applications involved text correction rounds, the time needed by Swissmedic to review the texts increased from 45 CD in 2021 to 81 CD in 2022. However, 2022 was also the first year that additional assessment cycles for answers to Swissmedic preliminary decisions were included in Swissmedic's time.

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

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

New applications for KAS without innovation can be submitted to Swissmedic two years before document protection for the original preparation expires. It is thus possible to issue decisions on authorisation within the applicable processing times.

Swissmedic's median throughput time for KAS without innovation in the standard procedure was comparable with the EMA's (452 CD vs 462 CD), but still significantly faster than the FDA's (1,971 CD). The procedure under Art. 13 TPA is applied to more than half of applications involving KAS without innovation, which accelerates the process by approx. 150 CD (2020: 315 CD; 2021: 257 CD; 2022: 305 CD).

Swissmedic's authorisation times for KAS with innovation were virtually unchanged on the previous year. In a multi-year comparison, this is an area where Swissmedic is on an equal footing with the EMA[5].

Overall, throughput times for procedures involving KAS with and without innovation exhibited variability.

It was not possible to record meaningful data on applications under Art. 14 para. 1 let. a$^{bis-quater}$ TPA and biosimilars for this year's study, since too few applications were received.

[5] No data for the FDA due to low numbers of evaluations for KAS applications with and without innovation