Executive Summary – Benchmarking 2021

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

In 2022, the pharmaceutical industry and Swissmedic conducted their ninth joint benchmarking study on approval times for human medicines. The aim of the comparison of the approval times of Swissmedic, the European Medicines Agency (EMA) and the US Food and Drug Administration (FDA) is to demonstrate the performance of Swissmedic as an independent national authorisation agency in relation to those of the two international reference authorities. As well as this international benchmarking, the study also contains a differentiated analysis of the national authorisation procedures.

This data analysis includes applications completed in the period from 1 January to 31 December 2021.

The current study also presents procedures involving international cooperation (Access Consortium, Project Orbis) in addition to national procedures. Submission gaps[1] and approval gaps[2] have been evaluated for the first time.

For the first time, there were sufficient numbers of temporary authorisations and procedures according to Art. 14 para. 1 let. a^{bis} TPA for a national evaluation.[3] By contrast, there were no decisions on new herbal medicines in 2021.

74 companies took part in this benchmarking study. They accounted for 77% of the overall market and 81% of the market for prescription-only medicines. These high percentages make it possible to draw meaningful conclusions.[4]

The results of the evaluations are broken down in more detail by application type and procedure below, and finally summarised in the Conclusion and outlook section.

New applications for new active substances

Authorisation procedure

At 10%, the share of accelerated authorisation procedures (FTP and PPN pooled) for NA NAS was well below the previous year's figure of 25%. By contrast, the share of Orbis and Access applications (pooled) rose considerably from 7% to 26%, and that of temporary authorisation procedures from 4% to 10%.

Lead times

The breakdown shows an acceleration in the throughput time[5] across all procedures from 427 calendar days (CD) to 391 CD (-8%). Swissmedic's throughput time was shorter than that of the EMA (401 CD, see Figure 1) for the first time.

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[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.

[3] By contrast, there were insufficient evaluable applications according to Art. 14 para. 1 let. a^{ter} and a^{quater} TPA.

[4] When comparing this Executive Summary and R&D Briefing 85 from CIRS, it should be noted that the inclusion criteria for applications are not identical, which may lead to numerical differences.

[5] All times are given in calendar days. The median is used as the average value for all figures. The terms “accelerated” and “faster” are used as synonyms for shorter throughput times.

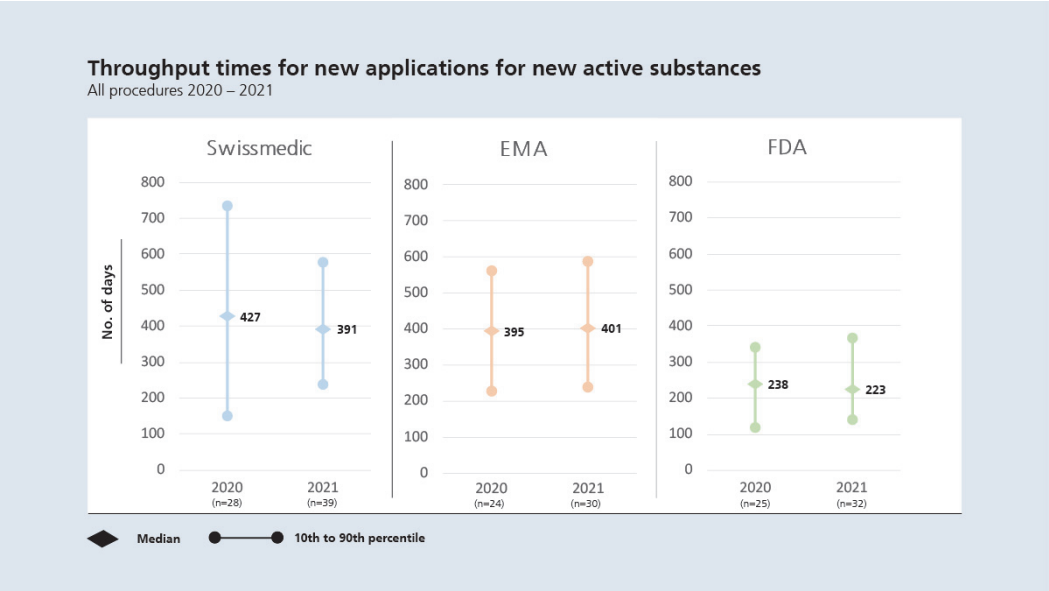

Figure 1: Comparison of throughput times of Swissmedic, the EMA and the FDA for all NA NAS procedures in 2020-2021 (median values with 10th and 90th percentiles).

The standard-procedure throughput time was 428 CD in Switzerland, a reduction of 20% on the previous year and also very close to that of the EMA (419 CD). Applications with orphan drug status took 394 CD in Switzerland, and were 26% faster than in 2020.

Among the international procedures, Orbis NAS applications (type A and C, pooled)[6] had a 33% shorter throughput time of 285 CD versus the standard procedure. Access NAS applications were 11% faster than the standard procedure at 382 CD.

Submission and approval gaps

The first-time evaluation of submission and approval gaps for the EMA and FDA found high submission gaps of 171 CD and 322 CD respectively from submissions to the EMA and FDA for NA NAS applications (see Figure 2). The approval gaps were 218 CD from approval by the EMA and 385 CD from approval by the FDA.

[6] A separate evaluation of Orbis type A and type C applications was not carried out due to insufficient numbers of applications. No Orbis type B applications were concluded in 2021.

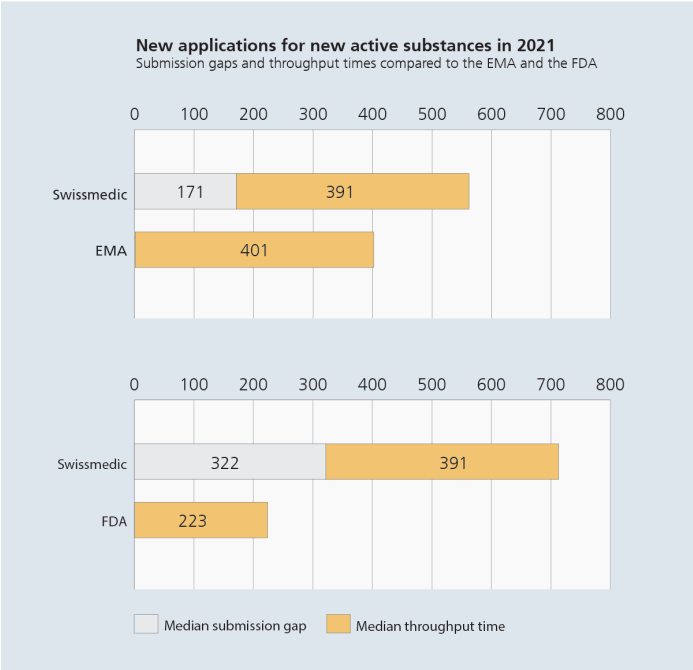

Figure 2: Submission gaps and throughput times of Swissmedic compared to the reference authorities, the EMA and the FDA (median values)

Submission gaps in the temporary authorisation procedures were somewhat shorter, at 152 CD from submission to the EMA and 192 CD from submission to the FDA. The products were authorised in Switzerland 21 CD earlier than the EMA and 316 CD later than the FDA.

As expected, the international Orbis and Access procedures had shorter submission gaps: For Orbis NA NAS, the submission gap from submission to the EMA was 46 CD and that from submission to the FDA 115 CD. Authorisation was a median of 39 CD earlier than the EMA and 216 CD later than the FDA. In the Access procedure, the submission gap from submission to the EMA was 53 CD and that from submission to the FDA 49 CD. Authorisation was 68 CD later than the EMA and 153 later than the FDA.

Additional indications

There were no signification changes across all procedures for additional indications (AI): Swissmedic's throughput time of 367 CD (+3%) continued to be longer than that of the EMA (282 CD) and FDA (183 CD) (see Figure 3).

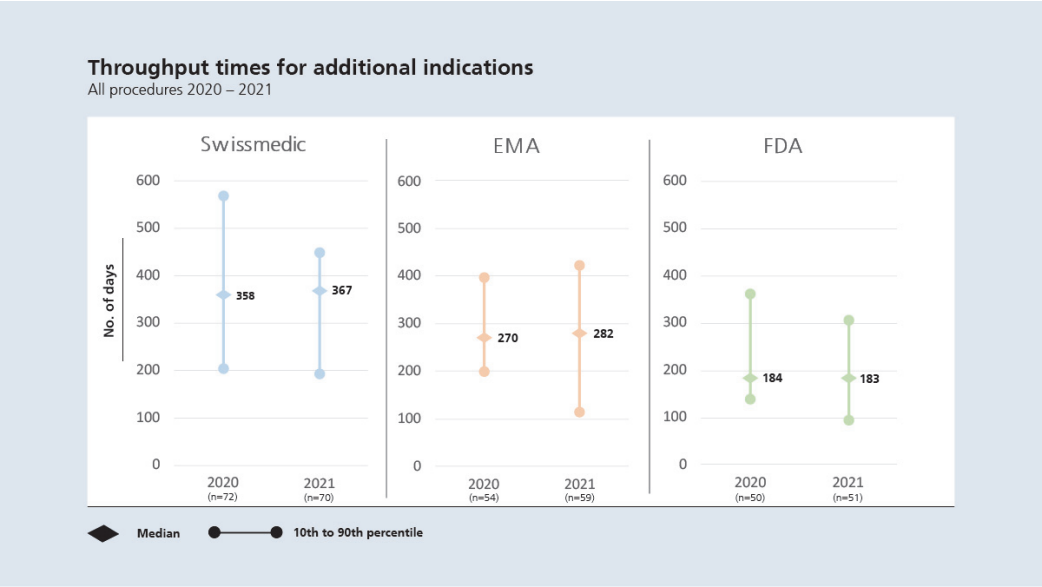

Figure 3: Comparison of throughput times of Swissmedic, the EMA and the FDA for all AI procedures in 2020-2021 (median values with 10th and 90th percentiles).

The submission gaps (EMA: 52 CD; FDA: 64 CD; see Figure 4) and approval gaps (EMA: 113 CD; FDA: 202 CD) were shorter overall for all AI applications.

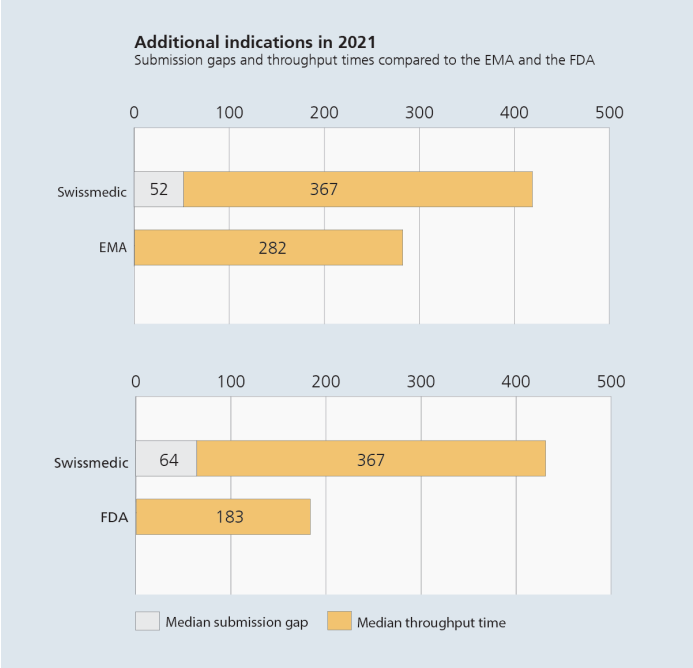

Figure 4: Submission gaps and throughput times of Swissmedic compared to the reference authorities, the EMA and the FDA (median values)

As expected, Orbis type A applications had particularly short throughput times of 195 CD (-48%). The submission gaps (1 CD from submission to the EMA; 13 CD from submission to the FDA) and approval gaps (-39 CD from approval by the EMA; 57 CD from approval by the FDA) were also shorter.

Known active substances without innovation (generics) and with innovation

The throughput time for KAS without innovation across all procedures was 352 CD (-6%) versus 439 CD (-2%) for the EMA.[7]

KAS without innovation according to Art. 13 TPA again had a shorter throughput time (257 CD, -18%) versus the standard procedure, and their share of all procedures rose to an impressive 65% (+19%).

The throughput time for KAS with innovation decreased to 463 CD (-16%) compared with 529 CD (13%) for the EMA.

18% of KAS with innovation were concluded in the procedure according to Art. 14 para. 1 let. a^{bis} TPA in 2021. The throughput time for these applications was 516 CD, i.e. 11% longer than the throughput time for NA KAS in the standard procedure.

Impact of measures to avoid text review rounds

Swissmedic introduced measures to reduce the number of text review rounds in July 2020[8]. These were applied to the majority of NA NAS (85%) and AI (90%) concluded in 2021. The evaluation showed a pleasing reduction of 39% for NA NAS applications and 43% for AI. Where there were nonetheless additional text review rounds, Swissmedic was able to reduce its review time in the standard procedure by 48% for NA NAS and by 24% for AI. The time savings achieved along with the greater use of Orbis and Access and other faster procedures helped considerably to shorten the overall throughput time.

Conclusion and outlook

This year's benchmarking results firstly show how the combination of submission gap and throughput time impact on the timely availability of medicinal products ("approval gap").

There was a positive trend overall regarding throughput time. With the exception of additional indications, the throughput time was once again reduced considerably compared to the previous year. For NA NAS in particular, Swissmedic was below the EMA's throughput time for all procedures for the first time. Authorisations of medicinal products for the treatment of rare diseases (orphan drugs) were also significantly faster.

A number of factors played a role in this positive trend, including the systematic implementation of measures to speed up the process by avoiding text review rounds, increased submission of temporary authorisations (including those for medicinal products for COVID-19, which were processed as rolling submissions in some cases) and more evaluations in international procedures (Orbis, Access).

For additional indications, there is still potential for improvement in terms of procedure duration and promoting the use of accelerated procedures (particularly PPN) and international procedures.

The submission gaps compared to the EMA and the FDA were surprising. Even though evaluation under international procedures contributed to reducing the submission gaps, there is still a need here for careful attention and analysis.

Overall, we expect that application processing under international procedures (Orbis, Access) will play an increasingly important role in the authorisation of innovative medicinal products, which will in turn have a positive effect on submission gaps, throughput times and approval gaps.

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

[8] See https://www.swissmedic.ch/swissmedic/en/home/humanarzneimittel/authorisations/information/optimierung_labelling-phase-ham.html