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# Authorisations of human medicinal products with a new active substance and additional indications

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# 1 Authorisation of human medicinal products with a new active substance

**In 2025, Swissmedic authorised 40 human medicinal products with new active substances.**

In 2025, Swissmedic concluded 45 new authorisation applications for human medicinal products with new active substances. Swissmedic authorised 40 (89%) of these and in five cases (11%) the application was withdrawn by the companies. All of the following figures relate exclusively to the 40 applications that were approved in 2025 (Table 1).

Table 1: Number of new authorisations of human medicinal products with new active substances. Breakdown by authorisation procedure and authorisation status

| Authorisation procedures | 2023 | | 2024 | | 2025 | |
|---|---|---|---|---|---|---|
| | Authorisation | Temporary authorisation | Authorisation | Temporary authorisation | Authorisation | Temporary authorisation |
| **Procedures with standard time limits** | **23** | **1** | **27** | **1** | **19** | **1** |
| Standard procedure | 14 | 1 | 16 | 0 | 11 | 1 |
| Reliance procedures[1] | 9 | 0 | 11 | 1[6] | 8[9] | 0 |
| **Fast-track procedures** | **11** | **6** | **14** | **4** | **19** | **1** |
| Fast-track authorisation procedure | 5[2,3] | 0 | 4 | 0 | 6[10] | 0 |
| Temporary authorisation procedure | 0 | 4[4,5] | 1 | 4[7] | 0 | 1 |
| Procedure with prior notification | 1 | 0 | 2 | 0 | 3[11] | 0 |
| Access | 4[2] | 0 | 5[8] | 0 | 8 | 0 |
| Orbis | 2 | 3[4] | 3 | 0 | 2 | 0 |
| **Subtotal** | **34** | **7** | **41** | **5** | **38** | **2** |
| **Total authorised NA NAS** | **41** | | **46** | | **40** | |

The NA NAS can be allocated to several procedures. The reported (sub-)total of NA NAS authorisations therefore does not correspond to the sum of the individual items. Details of multiple allocations are provided in the footnotes.

1 "Reliance procedures" combines all authorisations according to Art. 13 TPA and Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA.
2 1 NA NAS in the FTP and Access.
3 1 NA NAS in the FTP and according to Art. 13 TPA.
4 1 NA NAS temporary authorisation applied for in Project Orbis.
5 2 NA NAS temporary authorisations applied for in the procedure according to Art. 13 TPA.
6 3 NA NAS in the reliance procedure were submitted under the temporary authorisation procedure and are **not** included here.
7 3 NA NAS in the reliance procedure according to Art. 13 TPA.
8 1 application in the FTP.
9 2 NA NAS in the reliance procedure according to Art. 13 TPA were submitted under fast-track procedures (PPN and FTP) and are **not** included here.
10 1 NA NAS in the reliance procedure according to Art. 13 TPA.
11 1 NA NAS in the reliance procedure according to Art. 13 TPA.

Abbreviations: FTP: Fast-track authorisation procedure, TPA: Therapeutic Products Act, NA NAS: New application for new active substance, PPN: Procedure with prior notification.

The median turnaround time for the 40 applications was 392 calendar days (CD). Compared to 2024 (444 CD) the turnaround time decreased by 52 CD (12%).

Across all authorisations (temporary and non-limited), 50% (n=20) were approved in procedures with standard time limits and 50% (n=20) in fast-track procedures. As well as the fast-track authorisation procedure (FTP), these include the temporary authorisation procedure, the procedure with prior notification (PPN) and the international procedures Access and Orbis.

In 2025, temporary authorisations accounted for 5% (n=2) of the newly authorised medicinal products (2024: 11%).

## Procedures with standard time limits

The median turnaround time for applications in procedures with standard time limits (n=20) was 458 CD (2024: 477 CD, n=28) and was thus 82 CD below the maximum time limit of 540 CD.

30% (n=12) of all applications were processed in the standard procedure (2024: 35%, n=16). The median turnaround time was 480 CD (2024: 518 CD).

The reliance procedures according to Art. 13 TPA and Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA were used in 20% of all cases (n=8; 2024: 26%, n=12). The median turnaround time of the procedures according to Art. 13 TPA (n=7) was 391 CD (2024: 463 CD, n=10). One application was authorised in the procedure according to Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA, with a turnaround time of 257 CD (2024: 483 CD, n=2).

## Fast-track procedures

The median turnaround time for applications in fast-track procedures (n=20) was 338 CD (2024: 327 CD, n=18). Two of these were authorised in the reliance procedure according to Art. 13 TPA.

The FTP was used in 15% (n=6) of all applications. The median turnaround time was 288 CD (2024: 277 CD, n=4) while the maximum time limit is 350 CD.

Temporary authorisation was requested in one case, which was accordingly reviewed within a shorter time (2024: n=5). The median turnaround time for this application was 295 CD (max. time limit: 350 CD; median turnaround time 2024: 224 CD).

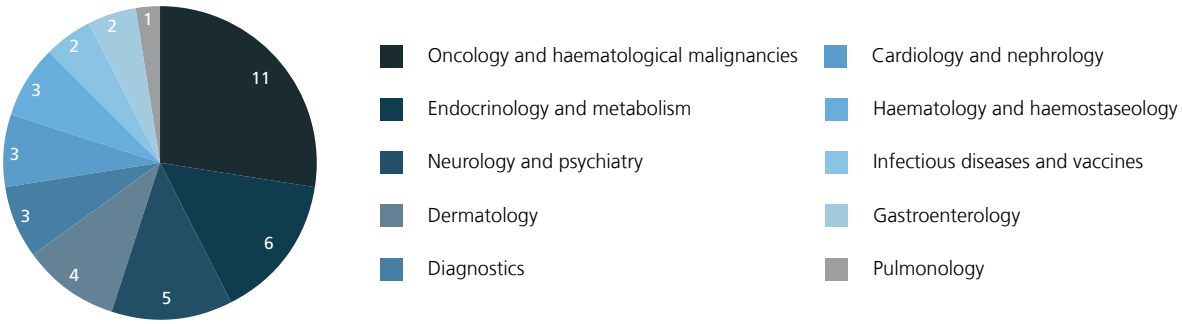
The PPN was applied in 8% of cases (n=3). The turnaround time was 327 CD (2024: 450 CD, n=2) and was thus 97 CD below the maximum time limit of 424 CD.

25% (n=10) of the authorisations were processed in connection with international procedures (2024: 17%; n=8):

- Eight medicinal products were authorised in the work-sharing procedure of the Access Consortium (2024: n=5). The median turnaround time for the Access applications was 395 CD (2024: 328 CD).
- In Project Orbis, two oncology medicines (type A: n=1; type B: n=1) were authorised (2024: n=3). The median turnaround time for the Orbis applications was 321 CD (2024: 329 CD).

# 2 Newly authorised medicinal products according to indication

Figure 1: Authorised medicinal products according to indication (n=40)




Overall, the distribution of indications is similar to the previous year, but with shifts in the prevalence of individual specialist fields: Medicinal products for *oncology and haematological malignancies* still represent the largest group (28%, n=11). *Endocrinology and metabolism* (15%, n=6) and *neurology and psychiatry* (13%, n=5) also remain among the most common indications. *Dermatology* (10%, n=4) and *cardiology and nephrology* (8%, n=3) increased compared to 2024. By contrast, *infectious diseases and vaccines* (5%, n=2) and *haematology and haemostaseology* (8%, n=3) decreased in 2025 and there were no ophthalmological medicinal products.

Table 2: : Authorised medicinal products by medicinal product, active substance(s) and indication (n=40)

| Medicinal product | Active substance(s) | Indication |
|---|---|---|
| **Oncology and haematological malignancies** | | |
| Balversa | Erdafitinib | Urothelial cancer |
| Blenrep | Belantamab mafodotin | Multiple myeloma |
| Datroway | Datopotamab deruxtecan | Breast cancer |
| Elahere | Mirvetuximab soravtansine | Ovarian, fallopian tube or primary peritoneal cancer |
| Hetronifly | Serplulimab | Lung cancer |
| Itovebi | Inavolisib | Breast cancer |
| Lazcluze | Lazertinib | Lung cancer |
| Nexpovio | Selinexor | Multiple myeloma |
| Vanflyta | Quizartinib | Acute myeloid leukaemia |
| Vyloy | Zolbetuximab | Stomach cancer |
| Zynyz | Retifanlimab | Merkel cell carcinoma |
| **Endocrinology and metabolism** | | |
| Imcivree | Setmelanotide | Obesity associated with Bardet-Biedl syndrome (BBS) |
| Lynkuet | Elinzanetant | Vasomotor symptoms in post-menopausal patients |
| Sephience | Sepiapterin | Phenylketonuria |
| Tepezza | Teprotumumab | Thyroid eye disease |
| Voxzogo | Vosoritide | Achondroplasia |
| Yorvipath | Palopegteriparatide | Hypoparathyroidism |
| **Neurology and psychiatry** | | |
| Briumvi | Ublituximab | Multiple sclerosis |
| Imaavy | Nipocalimab | Myasthenia gravis |
| Qalsody | Tofersen | Amyotrophic lateral sclerosis (ALS) |
| Rystiggo | Rozanolixizumab | Myasthenia gravis |
| Wainzua | Eplontersen | Polyneuropathy associated with amyloidosis |
| **Dermatology** | | |
| Filsuvez | Refined dry extract from birch bark | Epidermolysis bullosa |
| Litfulo | Ritlecitinib | Alopecia areata |
| Nemluvio | Nemolizumab | Atopic dermatitis |
| Relfydess | Botulinum toxin type A (strain I01) | Glabellar lines |

| Medicinal product | Active substance(s) | Indication |
|---|---|---|
| **Diagnostics** | | |
| PulmoProDiff | Carbon monoxide, helium | Investigating lung function |
| Pylclari | Piflufolastat (18F) | Diagnosis in prostate cancer |
| RoTecPSMA | Trofolastat | Diagnosis in prostate cancer |
| **Cardiology and nephrology** | | |
| Beyonttra | Acoramidis | Transthyretin amyloid cardiomyopathy (ATTR-CM) |
| Jeraygo | Aprocitentan | Arterial hypertension |
| Obgemsa | Vibegron | Overactive bladder |
| **Haematology and haemostaseology** | | |
| Andembry | Garadacimab | Hereditary angioedema |
| Ekterly | Sebetralstat | Hereditary angioedema |
| Piasky | Crovalimab | Paroxysmal nocturnal haemoglobinuria (PNH) |
| **Infectious diseases and vaccines** | | |
| Capvaxive | *Streptococcus pneumoniae* serotypes 3, 6A, 7F, 8, 9N, 10A, 11A, 12F, 15A, 15B de-O-acetylated, 16F, 17F, 19A, 20A, 22F, 23A, 23B, 24F, 31, 33F, 35B polysaccharide conjugated to *Corynebacterium diphtheriae* CRM197 protein | Prevention of *Streptococcus pneumoniae* infection |
| mRESVIA (respiratory syncytial virus mRNA vaccine) | mRNA-1345 | Prevention of respiratory syncytial virus (RSV) infection |
| **Gastroenterology** | | |
| Bylvay | Odevixibat | Progressive familial intrahepatic cholestasis |
| Lyvdelzi | Seladelpar | Primary biliary cholangitis |
| **Pulmonology** | | |
| Alyftrek | Vanzacaftor, tezacaftor, deutivacaftor | Cystic fibrosis |

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# 3 Authorisation of additional indications

**In 2025, Swissmedic authorised 109 additional indications**

In 2025, Swissmedic concluded 117 applications for additional indications. Swissmedic approved 109 (93%) of these and in eight cases (7%) the application was withdrawn by the companies. All of the following figures relate exclusively to the 109 applications that were approved in 2025 (Table 3).

The median turnaround time for the 109 applications, pooled across all procedures, was 331 CD. Compared to 2024 (316 CD, n=71) the turnaround time increased by 15 CD or 5%.

Table 3: Number of additional indications. Breakdown by authorisation procedure and authorisation status

| **Authorisation procedures** | **2023** | | **2024** | | **2025** | |
|---|---|---|---|---|---|---|
| | Authorisation | Temporary authorisation | Authorisation | Temporary authorisation | Authorisation | Temporary authorisation |
| **Procedures with standard time limits** | **52** | **1** | **48** | **0** | **74** | **3** |
| Standard procedure | 46[2] | 1 | 44 | 0 | 70 | 2 |
| Reliance procedures[1] | 6 | 0 | 4 | 0 | 4[5,6] | 1 |
| **Fast-track procedures** | **12** | **0** | **23** | **0** | **29** | **4** |
| Fast-track authorisation procedure | 1[3] | 0 | 1[3] | 0 | 6[3] | 1 |
| Temporary authorisation procedure | 0 | 0 | 3 | 0 | 0 | 2[8] |
| Procedure with prior notification | 2 | 0 | 3 | 0 | 4[7] | 0 |
| Access | 1 | 0 | 3 | 0 | 8[4] | 0 |
| Orbis | 9[4] | 0 | 14[4] | 0 | 12[4] | 1 |
| **Subtotal** | **64** | **1** | **71** | **0** | **94** | **7** |
| **Total authorised AI** | **65** | | **71** | | **109** | |

The AI can be allocated to several procedures. The reported (sub-)total of AI authorisations therefore does not correspond to the sum of the individual items. Details of multiple allocations are provided in the footnotes.

[1] "Reliance procedures" combines all authorisations according to Art. 13 TPA and Art. 14 para. 1 let. a[bis-quater] TPA.
[2] 1 temporary AI authorisation.
[3] 1 AI in Project Orbis.
[4] 1 AI in the FTP.
[5] 2 AI in the reliance procedure according to Art. 13 TPA were submitted under the temporary authorisation procedure and are **not** included here.
[6] 1 AI in the reliance procedure according to Art. 13 TPA was submitted as a PPN and is **not** included here.
[7] 1 AI authorised in the reliance procedure according to Art. 13 TPA.
[8] Both AI authorised in the reliance procedure according to Art. 13 TPA.

Abbreviations: FTP: Fast-track authorisation procedure, TPA: Therapeutic Products Act, AI: Additional indication, PPN: Procedure with prior notification.

71% (n=77) of the applications were authorised in procedures with standard time limits (2024: 68%, n=48). 29% (n=32) of the applications were authorised in fast-track procedures (FTP, PPN or the international procedures Access and Orbis; 2024: 32%, n=23).

## Procedures with standard time limits

The median turnaround time for additional indications in procedures with standard time limits (n=77) was 377 CD and was thus 73 CD below the maximum time limit of 450 CD (2024: 333 CD).

66% (n=72) of all additional indications (2024: 62%) were processed in the standard procedure. The median turnaround time was 383 CD (2024: 348 CD).

The reliance procedure according to Art. 13 TPA was employed in 5% (n=5) of all cases (2024: 6%). The median turnaround time was 241 CD (2024: 270 CD).

## Fast-track procedures

The median turnaround time for applications in fast-track procedures (n=32) was 258 CD (2024: 268 CD, n=23). Three of these were authorised in the reliance procedure according to Art. 13 TPA.

The FTP was used in 6% (n=7) of all applications. The median turnaround time was 201 CD (max. time limit: 320 CD; median turnaround time 2024: 132 CD).

Temporary authorisation was requested by applicants in 2% (n=2) of all cases, which were thus reviewed within a shorter time. The median turnaround time for these applications was 117 CD (max. time limit: 320 CD; median turnaround time 2024: 188 CD).

The PPN, with a 20% shorter review time by Swissmedic, was applied in four cases (4%). The median completion time for additional indications in the PPN in 2025 was 229 CD (max. time limit: 346 CD; 2024: 157 CD).

19% (n=21) of all additional indications (2024: 24%, n=17) were authorised in connection with international procedures:

- Eight indication extensions (2024: n=3) were authorised in the work-sharing procedure of the Access Consortium. The turnaround time for these applications was 319 CD (2024: 323 CD).
- Thirteen additional indications (type A: n=10, type B: n=2; type C: n=1; 2024: n=14) for oncology medicines were authorised in Project Orbis during 2025. The median turnaround time for the Orbis applications was 249 CD (2024: 255 CD).

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