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

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Credits

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1 Authorisation of human medicinal products with a new active substance

In 2024, Swissmedic authorised 46 human medicinal products with new active substances.

In 2024, Swissmedic concluded 54 new authorisation applications for human medicinal products with new active substances. Swissmedic authorised 46 (85%) of these and in eight cases (15%) the application was withdrawn by the companies. All of the following figures relate exclusively to the 46 applications that were approved in 2024 (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	2022		2023		2024	
	Authorisation	Temporary authorisation	Authorisation	Temporary authorisation	Authorisation	Temporary authorisation
Procedures with standard time limits	**22**	**5**	**23**	**1**	**27**	**1**
Standard procedure	15	2	14	1	16	0
Reliance procedures[1]	7	3	9	0	11	1[6]
Fast-track procedures	**11**	**9**	**11**	**6**	**14**	**4**
Fast-track authorisation procedure	2	1	5[2,3]	0	4	0
Temporary authorisation procedure	0	4	0	4[4,5]	1	4[7]
Procedure with prior notification	2	1	1	0	2	0
Access	6	0	4[2]	0	5[8]	0
Orbis	1	3	2	3[4]	3	0
Subtotal	**33**	**14**	**34**	**7**	**41**	**5**
Total authorised NA NAS	**47**		**41**		**46**	

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-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] Including 3 NA NAS in the Reliance procedure according to Art. 13 TPA.
[8] Including 1 application in the FTP.

The median turnaround time for all 46 applications was 444 calendar days (CD). Compared to 2023 (441 CD) the turnaround time remained stable, deviating by +3 CD or +1%.

Across all authorisations (temporary and non-limited), 61% (n=28) were approved in procedures with standard time limits and 39% (n=18) 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 2024, temporary authorisations accounted for 11% (n=5) of the newly authorised medicinal products (2023: 17%).

Procedures with standard time limits

The median turnaround time for applications in procedures with standard time limits (n=28) was 477 CD and was thus 63 CD below the maximum time limit of 540 CD (Annex, Guidance document Time limits for authorisation applications).

35% (n=16) of all applications were processed in the standard procedure. The median turnaround time was 518 CD (2023: 464 CD).

The reliance procedures according to Art. 13 TPA and Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA were used in 26% of all cases (n=12; 2023: 22%, n=9). The median turnaround time of the procedures according to Art. 13 TPA (n=10) was 463 CD. The median turnaround time for procedures according to Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA (n=2) was 483 CD.

Fast-track procedures

The median turnaround time for applications in accelerated procedures (n=18) was 327 CD.

The FTP was used in 9% (n=4) of all applications. The median turnaround time was 277 CD (2023: 290 CD), while the maximum time limit is 350 CD.

Temporary authorisation was requested by applicants in 11% (n=5) of all cases, which were thus reviewed within a shorter time. The median turnaround time for these applications was 224 CD (max. time limit: 350 CD; median turnaround time 2023: 245 CD).

The PPN was applied in 4% of cases (n=2). The turnaround time was 450 CD (2023: 548 CD) and was thus 26 CD above the maximum time limit of 424 CD.

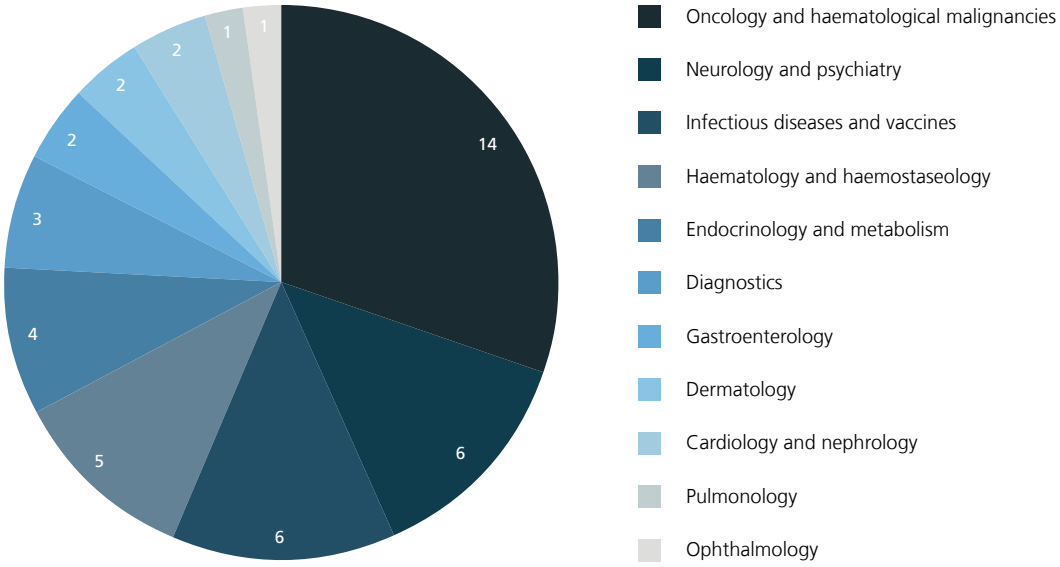
17% (n=8) of the authorisations were processed in connection with international procedures (2023: 22%, n=9):

- Five medicinal products were authorised in the work-sharing procedure of the Access Consortium (2023: n=4), one of which was applied for and assessed in the FTP. The median turnaround time for the Access applications was 328 CD (2023: 403 CD).

- In Project Orbis, n=3 oncology medicines were authorised (2023: n=5). The median turnaround time for the Orbis applications was 329 CD (2023: 341 CD).

2 Newly authorised medicinal products according to indication

Figure 1: Authorised medicinal products according to indication (n=46)



Overall, the distribution of indications is stable compared to the previous year, with moderate shifts within specialist fields. Medicinal products for *oncology and haematological malignancies* still represent the largest group (30%, n=14). *Infectiology and vaccines* (13%, n=6) and *haematology and haemostaseology* (11%, n=5) also remain among the most common indications. A new leading indication for 2024 is *neurology and psychiatry* (13%, n=6).

Table 2: Authorised medicinal products by medicinal product, active substance(s) and indication (n=46)

Medicinal product	Active substance(s)	Indication
Oncology and haematological malignancies		
Ebvallo	Tabelecleucel	Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD)
Enrylaze	Crisantaspase	Acute lymphoblastic leukaemia (ALL), lymphoblastic lymphoma (LBL)
Fruzaqla	Fruquintinib	Colorectal cancer
Lutathera 370 MBq/ml	Lutetium (177Lu) oxodotreotide	Gastroenteropancreatic neuroendocrine tumours (GEP NETs)
Lytgobi	Futibatinib	Cholangiocarcinoma
Omjjara	Momelotinib	Myelofibrosis
Orserdu	Elacestrant	Breast cancer
Qarziba	Dinutuximab beta	Neuroblastoma
Tepkinly	Epcoritamab	Diffuse large B-cell lymphoma (DLBCL)
Tevimbra	Tislelizumab	Oesophageal squamous cell carcinoma
Tibsovo	Ivosidenib	Acute myeloid leukaemia (AML)
Truqap	Capivasertib	Breast cancer
Voranigo	Vorasidenib	Astrocytoma, oligodendroglioma
Welireg	Belzutifan	Von Hippel-Lindau (VHL) disease
Neurology and psychiatry		
Aquipta	Atogepant	Migraine
Desveneurax	Desvenlafaxine	Depression
Skyclarys	Omaveloxolone	Friedreich's ataxia
Uplizna	Inebilizumab	Neuromyelitis optica spectrum disorder (NMOSD)
Vyvgart	Efgartigimod alfa	Myasthenia gravis
Zilbrysq	Zilucoplan	Myasthenia gravis
Infectious diseases and vaccines		
Abrysvo	RSV antigen	Prevention of respiratory syncytial virus (RSV) infection
Arexvy	RSV antigen	Prevention of respiratory syncytial virus (RSV) infection
Hepcludex	Bulevirtide	Chronic hepatitis delta virus (HDV) infection
Jynneos	Modified vaccinia virus (live, attenuated)	Prevention of smallpox, monkeypox and vaccinia virus infection
Prevenar 20	Pneumococcal polysaccharide conjugate vaccine	Prevention of Streptococcus pneumoniae infection
Qdenga	Dengue virus (live, attenuated)	Prevention of dengue fever

Medicinal product	Active substance(s)	Indication
Haematology and haemostaseology		
Altuvoct	Efanesoctocog alfa	Factor VIII deficiency
Casgevy	Exagamglogen autotemcel	Beta thalassemia
Fabhalta	Iptacopan	Paroxysmal nocturnal haemoglobinuria (PNH)
Hympavzi	Marstacimab	Factor VIII/IX deficiency
Voydeya	Danicopan	Paroxysmal nocturnal haemoglobinuria (PNH)
Endocrinology and metabolism		
Awiqli FlexTouch	Insulin icodec	Diabetes mellitus
Pombiliti	Cipaglucosidase alfa	Acid alpha-glucosidase deficiency (Pompe disease)
Sogroya	Somapacitan	Growth hormone deficiency
Tymlos	Abaloparatide	Osteoporosis
Diagnostics		
18F-PSMA-1007 ZRP	[18F]PSMA-1007	Prostate cancer
Radelumin	[18F]PSMA-1007	Prostate cancer
SWAN-PSMA-1007	[18F]PSMA-1007	Prostate cancer
Gastroenterology		
Livmarli	Maralixibat	Cholestatic pruritus in Alagille syndrome (ALGS)
Velsipity	Etrasimod	Ulcerative colitis
Dermatology		
Anzupgo	Delgocitinib	Chronic hand eczema (CHE)
Ebglyss	Lebrikizumab	Atopic dermatitis
Cardiology and nephrology		
Filspari	Sparsentan	Immunoglobulin A nephropathy (IgAN)
Winrevair	Sotatercept	Pulmonary arterial hypertension
Pulmonology		
Levocalm	Levodropropizine	Dry cough
Ophthalmology		
Raxone	Idebenone	Leber's hereditary optic neuropathy (LHON)

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3 Authorisation of additional indications

In 2024, Swissmedic authorised 71 additional indications

In 2024, Swissmedic concluded 76 applications for additional indications. Swissmedic approved 71 (93%) of these and in five cases (7%) the application was withdrawn by the companies. All of the following figures relate exclusively to the 71 applications that were approved in 2024 (Table 3).

The median turnaround time for the 71 applications, pooled across all procedures, was 316 CD. Compared to 2023 (352 CD) the turnaround time fell by 36 CD or 10%.

68% (n=48) of the applications were authorised in procedures with standard time limits and 32% (n=23) in accelerated procedures (FTP, PPN or the international procedures Access and Orbis).

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

Authorisation procedures	2022	2023	2024
Procedures with standard time limits	49	53	48
Standard procedure	46	47[2]	44
Reliance procedures[1]	3	6	4
Fast-track procedures	15	12	23
Fast-track authorisation procedure	2	1[3]	1[3]
Temporary authorisation procedure	0	0	3
Procedure with prior notification	4	2	3
Access	1	1	3
Orbis	8	9[4]	14[4]
Total authorised AI	**64**	**65**	**71**

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.

Abbreviations: FTP: Fast-track authorisation procedure, TPA: Therapeutic Products Act, AI: additional indication.

Procedures with standard time limits

The median turnaround time for additional indications in procedures with standard time limits (n=48) was 333 CD and was thus 117 CD below the maximum time limit of 450 CD.

62% (n=44) of all additional indications (2023: 72%) were processed in the standard procedure. The median turnaround time was 348 CD (2023: 369 CD).

The Reliance procedure according to Art 13 TPA was employed in 6% of all cases (n=4). The median turnaround time was 270 CD (2023: 190 CD).

Fast-track procedures

The median turnaround time for applications in accelerated procedures (n=23) was 268 CD.

The FTP was used in one case (1%). The turnaround time was 132 CD (max. time limit: 320 CD; median turnaround time 2023: 199 CD).

Temporary authorisation was requested by applicants in 4% (n=3) of all cases, which were thus reviewed within a shorter time. The median turnaround time for these applications was 188 CD (max. time limit: 320 CD).

The PPN, with a 20% shorter review time by Swissmedic, was applied in three cases (4%). The median completion time for additional indications in the PPN in 2024 was 157 CD (max. time limit: 346 CD; 2023: 290 CD).

24% (n=17) of all additional indications (2023: 15%) were authorised in connection with international procedures:

- Three additional indications (2023: n=1) were authorised in the work-sharing procedure of the Access Consortium. The turnaround time for these applications was 323 CD (2023: 304 CD).

- 14 additional indications (2023: n=9) for oncology medicines were authorised in Project Orbis during 2024. The median turnaround time for the Orbis applications was 255 CD (2023: 302 CD).

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