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

2023

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Authorisation of human medicinal products with a new active substance

In 2023, Swissmedic authorised 41 human medicinal products with new active substances

In 2023, Swissmedic concluded 49 new authorisation applications for human medicinal products with new active substances. Swissmedic authorised 41 (84%) of these and in eight cases (16%) the application was withdrawn by the companies. All of the following figures relate exclusively to the 41 applications that were approved in 2023 (Table 1).

The median turnaround time for all 41 applications was 441 calendar days (CD). Compared to 2022 (456 CD) the turnaround time decreased by 15 CD or 3%.

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

Authorisation procedures	2021		2022		2023	
	Authorisation	Temp Auth.	Authorisation	Temp Auth.	Authorisation	Temp Auth.
Procedures with standard time limits	**27**	**5**	**22**	**5**	**23**	**1**
Standard procedure	19	3	15	2	14	1
Reliance procedures[1]	8	2	7	3	9	0
Fast-track procedures	**7**	**6**	**11**	**9**	**11**	**6**
Fast-track authorisation procedure	2	1	2	1	5[2,3]	0
Temporary authorisation procedure	0	1	0	4	0	4[4,5]
Procedure with prior notification	1	0	2	1	1	0
Access	3	0	6	0	4[2]	0
Orbis	1	4	1	3	2	3[4]
Subtotal	34	11	33	14	34	7
Total authorised NA NAS	**45**		**47**		**41**	

The NA NAS in 2023 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] 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.

Abbreviations: FTP: Fast-track authorisation procedure, TPA: Therapeutic Products Act, NA NAS: New application for new active substance

Across all authorisations (temporary and unlimited), 59% (n=24) were approved in procedures with standard time limits and 41% (n=17) 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 2023, temporary authorisations accounted for 17% (n=7) of the newly authorised medicinal products (2022: 30%).

Procedures with standard time limits

- The median processing time for applications in procedures with standard time limits (n=24) was 486.5 CD and was thus 53.5 CD below the maximum time limit of 540 CD (Annex 1, Guidance document *Time limits for authorisation applications*).

- 37% (n=15) of all applications were processed in the standard procedure. The median turnaround time was 464 CD (2022: 498 CD).

- The reliance procedures according to Art. 13 TPA and Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA were used in 22% of cases (n=9; 2022: 21%, n=10). The median processing time of the procedures according to Art. 13 TPA (n=5) was 406 CD. The median processing time for procedures according to Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA (n=4) was 621 CD.

Fast-track procedures

- The median processing time for applications in accelerated procedures (n=17) was 328 CD.

- The fast-track authorisation procedure was used in 12% (n=5) of cases. The median turnaround time was 290 CD (max. time limit: 350 CD; 2022: 333 CD).

- Temporary authorisation was requested by applicants for four medicinal products (10%), which were thus reviewed within a shorter time. The median turnaround time for these applications was 244.5 CD (max. time limit: 350 CD; 2022: 211 CD). In addition to the four temporary authorisation applications, three further human medicinal products with a new active substance were temporarily authorised.

- The PPN was applied in 2% of cases (n=1). Due to a procedural delay, the turnaround time was 548 CD (2022: 439 CD) and was thus 124 CD above the maximum time limit of 424 CD.

- 22% (n=9) of the authorisations were processed in connection with international procedures (2022: 21%):

  - Four medicinal products were authorised in the work-sharing procedure of the Access Consortium (2022: n=6), one of which was applied for and assessed in the FTP. The median turnaround time for the Access applications was 403 days (2022: 340 CD).

  - In Project Orbis, five oncology medicines (2022: n=5) were authorised, one of which was an application for temporary authorisation and thus reviewed within a shorter time. The median turnaround time for the Orbis applications was 341 CD (2022: 403 CD).

Newly authorised medicinal products according to indication

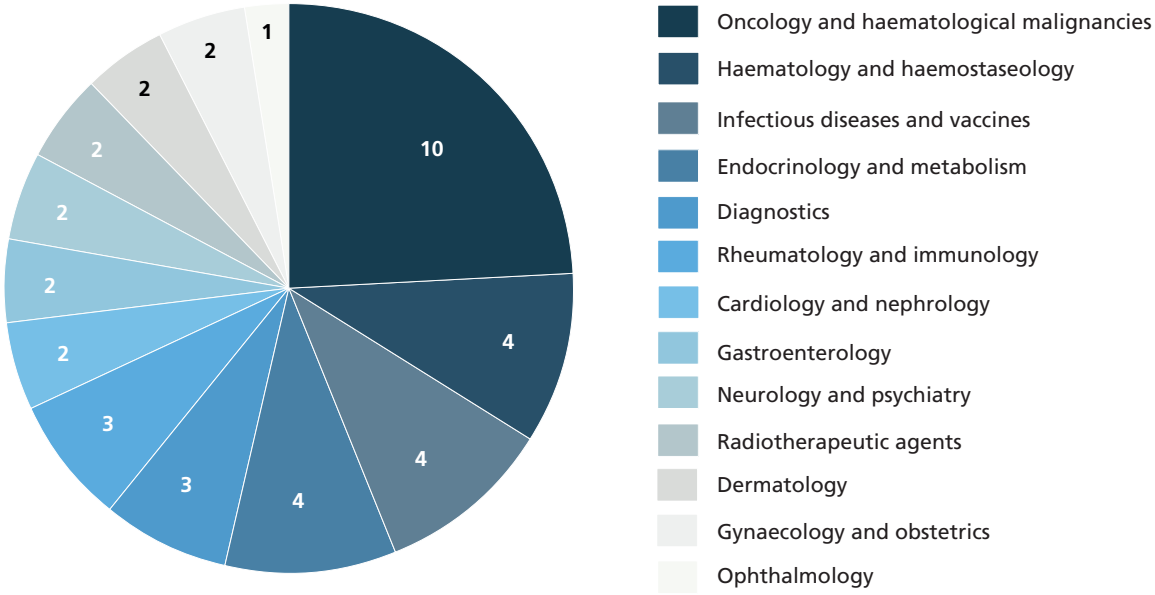

Figure 1: Authorised medicinal products according to indication (n=41)

The distribution of the indications is comparable to that of the previous year. At 24% (n=10), the largest group is made up of medicinal products for *oncology and haematological neoplasia*, followed by the three equal-sized groups of *haematology and haemostaseology* (10%, n=4), *infectiology and vaccines* (10%, n=4) and *endocrinology and metabolism* (10%, n=4).

Table 2: Authorised medicinal products by medicinal product, active substance(s) and use (n=41).

Oncology and haematological malignancies

Medicinal product	Active substance(s)	Indication
Jaypirca	Pirtobrutinib	Mantle cell lymphoma (MCL)
Ayvakyt	Avapritinib	Gastrointestinal stromal tumours (GIST)
Lunsumio	Mosunetuzumab	Follicular lymphoma
Elrexfio	Elranatamab	Multiple myeloma
Talvey	Talquetamab	Multiple myeloma
Imjudo	Tremelimumab	Hepatocellular carcinoma
Columvi	Glofitamab	Diffuse large B-cell lymphoma (DLBCL)
Elzonris	Tagraxofusp	Blastic plasmacytoid dendritic cell neoplasm (BP-DCN)
Zepzelca	Lurbinectedin	Small cell lung cancer (SCLC)
Kimmtrak	Tebentafusp	Uveal melanoma

Haematology and haemostaseology

Medicinal product	Active substance(s)	Indication
Alhemo	Concizumab	Factor IX deficiency
Hemgenix	Etranacogene dezaparvovec	Factor IX deficiency
Aspaveli	Pegcetacoplan	Paroxysmal nocturnal haemoglobinuria (PNH)
Enjaymo	Sutimlimab	Cold agglutinin disease

Infectious diseases and vaccines

Medicinal product	Active substance(s)	Indication
Livtencity	Maribavir	Cytomegalovirus (CMV) infection/illness following stem cell/organ transplants
Sunlenca	Lenacapavir	HIV-1 infection
Beyfortus	Nirsevimab	Prevention of respiratory syncytial virus (RSV) infection
Vaxneuvance	Pneumococcal polysaccharide conjugate vaccine	Active immunisation for the prevention of *Streptococcus pneumoniae* infection

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Endocrinology and metabolism

Medicinal product	Active substance(s)	Indication
milgamma	Benfotiamine	Vitamin B1 deficiency
Elfabrio	Pegunigalsidase alfa	Alpha-galactosidase A deficiency (Fabry disease)
Libmeldy	Atidarsagene autotemcel	Metachromatic leukodystrophy
Xenpozyme	Olipudase alfa	Acid sphingomyelinase deficiency (Niemann-Pick disease)

Diagnostics

Medicinal product	Active substance(s)	Indication
Verdye	Indocyanine green	Cardiovascular and microcirculation, hepatic function, ocular blood flow
Elucirem	Gadopiclenol	CNS and other parts of the body
Locametz	Gozetotide	Prostate cancer

Rheumatology and immunology

Medicinal product	Active substance(s)	Indication
Spevigo	Spesolimab	Generalised pustular psoriasis
Lupkynis	Voclosporin	Lupus nephritis
Condrosulf Plus	Chondroitin sulfate, glucosamine	Gonarthrosis

Cardiology and nephrology

Medicinal product	Active substance(s)	Indication
Vafseo	Vadadustat	Symptomatic anaemia associated with chronic kidney disease
Camzyos	Mavacamten	Symptomatic obstructive hypertrophic cardiomyopathy (oHCM)

Gastroenterology

Medicinal product	Active substance(s)	Indication
Spaverin	Drotaverine	Functional disorders of the gastrointestinal tract
Omvoh	Mirikizumab	Ulcerative colitis

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Neurology and psychiatry

Medicinal product	Active substance(s)	Indication
Vydura	Rimegepant	Migraine
Amvuttra	Vutrisiran	Hereditary transthyretin amyloidosis (hATTR amyloidosis) with polyneuropathy

Radiotherapeutic agents

Medicinal product	Active substance(s)	Indication
Pluvicto	Lutetium (^{177}Lu) vipivotide tetraxetan	Prostate cancer (mCRPC)
Pluvicto CA	Lutetium (^{177}Lu) vipivotide tetraxetan	Prostate cancer (mCRPC)

Dermatology

Medicinal product	Active substance(s)	Indication
Letybo	Botulinum toxin type A (CBFC26 strain)	Vertical lines between the eyebrows
Nuceiva	Botulinum toxin type A (from *Clostridium botulinum* strain KCDC)	Vertical lines between the eyebrows

Gynaecology and obstetrics

Medicinal product	Active substance(s)	Indication
Veoza	Fezolinetant	Vasomotor symptoms (VMS) in postmenopausal patients
Ryeqo	Relugolix, estradiol, norethisterone	Heavy menstrual bleeding associated with uterine fibroids

Ophthalmology

Medicinal product	Active substance(s)	Indication
Roclanda	Lantanoprost and netarsudil	Elevated intraocular pressure associated with primary open-angle glaucoma or ocular hypertension

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Authorisation of additional indications

In 2023, Swissmedic authorised 65 additional indications

In 2023, Swissmedic concluded 79 applications for additional indications. Swissmedic authorised 65 (82%) of these; in 13 cases (16%) the application was withdrawn by the companies and in one case (1%) there was a partial withdrawal. All of the following figures relate exclusively to the 65 applications that were approved in 2023 (Table 3).

The median turnaround time for the 65 applications, pooled across all procedures, was 352 CD (2022: 345 CD). 82% (n=53) of the applications were authorised in procedures with standard time limits and 18% (n=12) in accelerated procedures (FTP, PPN or the international procedures Access and Orbis).

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

Authorisation procedures	2021	2022	2023
Procedures with standard time limits	68	49	53
Standard procedure	58	46	47[2]
Reliance procedures[1]	10	3	6
Fast-track procedures	16	15	12
Fast-track authorisation procedure	2	2	1[3]
Procedure with prior notification	7	4	2
Access	0	1	1
Orbis	7	8	9[3]
Total authorised AI	**84**	**64**	**65**

The AI in 2023 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. abis-quater TPA.
[2] 1 Temporary AI authorisations
[3] 1 AI in the FTP and Project Orbis.

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

Procedures with standard time limits

- The median processing time for applications in procedures with standard time limits (n=53) was 352 CD and was thus 98 CD below the maximum time limit of 450 CD.
- 72% (n=47) of the additional indications (2022: 27%) were processed in the standard procedure. The median turnaround time was 369 CD (2022: 360 CD).
- Reliance procedures according to Art 13 TPA were employed in 9% of cases (n=6). The median turnaround time was 190 CD (2022: 237 CD).

Fast-track procedures

- The median processing time for applications in fast-track procedures (n=12) was 303 CD.
- The FTP was used in one case (2%). The turnaround time was 199 CD (max. time limit: 320 CD; 2022: 302 CD).
- The PPN, with a 20% shorter review time by Swissmedic, was applied in two cases (3%). The median completion time for additional indications in the PPN in 2023 was 289.5 CD (max. time limit: 346 CD; 2022: 313 CD).
- 15% (n=10) of the additional indications (2022: 14%) were authorised in connection with *international procedures*:
  - One additional indication (2022: n=1) was authorised in the work-sharing procedure of the Access Consortium. The turnaround time for this application was 304 CD.
  - In Project Orbis, nine additional indications (2022: n=8) for oncology medicines were authorised. The median turnaround time for the Orbis applications was 302 CD (2022: 259 CD)

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