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

2022

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Authorisation of human medicinal products with a new active substance

Authorisation procedures	2020		2021		2022	
	Authorisation	Temp Auth.	Authorisation	Temp Auth.	Authorisation	Temp Auth.
Procedures with standard time limits						
Standard procedure	16	5	19	3	15	2
Reliance procedures*	5	0	8	2	7	3
Fast-track procedures						
Fast-track authorisation procedure	7	0	2	1	2	1
Temporary authorisation procedure	0	2	0	1	0	4
Procedure with prior notification	5	0	1	0	2	1
Access	1	0	3	0	6	0
Orbis	1	0	1	4	1	3
Subtotal	35	7	34	11	33	14
Total	**42**		**45**		**47**	

*«Reliance procedures» combines all authorisations according to Art. 13 TPA and Art. 14 para. 1 let. a$^{bis-quater}$ TPA.

Number of new authorisations rises to 47

In 2022, Swissmedic authorised 47 human medicinal products with new active substances.

The median turnaround time for all 47 applications was 456 calendar days (CD). Compared to 2021 (396 CD) the turnaround time increased by 60 CD or 15%. The increased time needed is primarily attributable to those applications that were submitted and processed during the intensive pandemic years 2020/2021 and completed in 2022. During this time, applications for medicinal products to combat or prevent the pandemic were prioritised at the expense of other innovative new applications.

Across all authorisations (temporary and unlimited), 57% (n=27) were approved in procedures with standard time limits and 43% (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 2022, temporary authorisations accounted for 30% (n=14) of the newly authorised medicinal products (2021: 25%) and these are shown separately for the first time.

Procedure with standard time limits

- 36% (n=17) of all applications were processed in the standard procedure. The median turnaround time was 498 CD (2021: 482 CD).

- In 21% of cases (n=10), the reliance procedures according to Art. 13 TPA and Art. 14 para. 1 let. a$^{bis\text{-}quater}$ TPA were used, with a median turnaround time of 492 CD (2021: 332 CD).

Fast-track procedures

- The fast-track authorisation procedure was used in 6% (n=3) of cases. The median turnaround time was 333 CD (2021: 207 CD).

- Four of the 14 temporary authorisations (9%) were requested by companies for a limited period and were thus reviewed within a shorter time. The median turnaround time for these applications was 211 CD (2021: 238 CD).

- The PPN, with a 20% shorter review time by Swissmedic, was applied in 6% of cases (n=3). The median turnaround time was 439 CD (2021: 305 CD).

- 21% (n=10) of the authorisations were processed in connection with international procedures (2021: 18%):

  - Six (2021: 5) medicinal products were authorised in the work-sharing procedure of the Access Consortium. The median turnaround time for the Access applications was 340 days (2021: 392 CD).

  - In Project Orbis, 4 oncology medicines (2021: 6) were authorised. The median turnaround time for the Orbis applications was 403 CD (2021: 285 CD).

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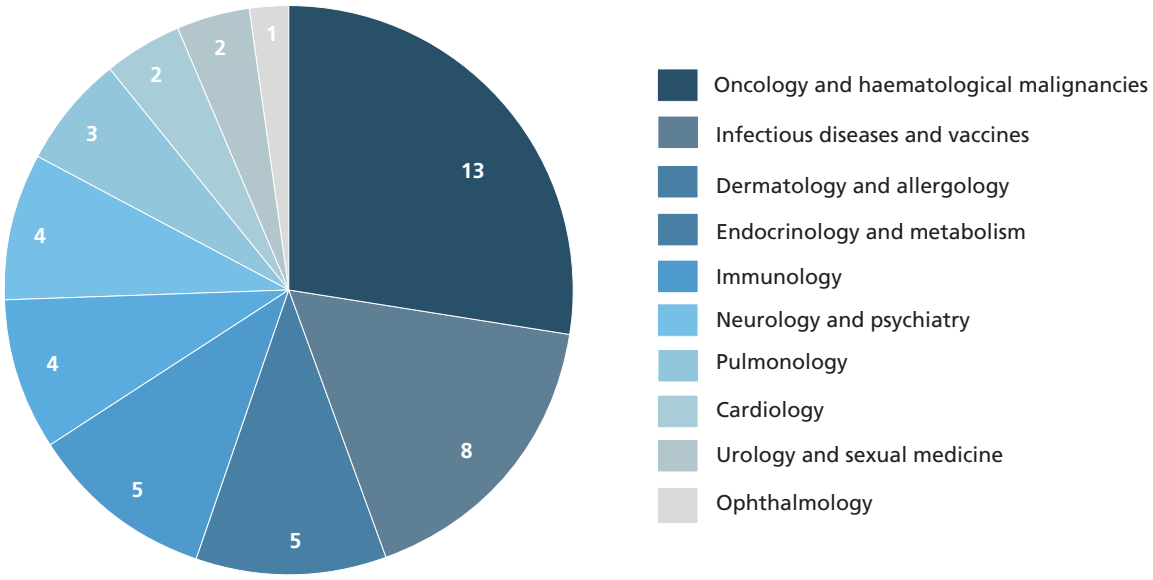
Authorised medicinal products according to indication

Figure 1
Authorised medicinal products according to indication (N=47)



The indications are more widely distributed compared to the previous year. Oncology and haematological malignancies again formed the largest group, accounting for 28% (n=13) of authorised medicinal products (-14% compared to 2021), followed by the groups of infectious diseases and vaccines (22%, n=8; -5% compared to 2021) and dermatology and allergology (11%, n=5; +9% compared to 2021).

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Oncology and haematological malignancies

Medicinal product	Active substance(s)	Anwendung
BCG Apogepha	*Bacillus Calmette-Guérin*, live, attenuated (Moreau strain)	Urothelial carcinoma of the bladder
Blenrep	Belantamab mafodotin	Multiple myeloma
Breyanzi	Lisocabtagene maraleucel	Large B-cell lymphomas (DLBCL, PMBCL)
Brukinsa	Zanubrutinib	Waldenström's macroglobulinaemia
Carvykti	Ciltacabtagene autoleucel	Multiple myeloma
Exkivity	Mobocertinib	Non-small cell lung cancer (NSCLC)
Jemperli	Dostarlimab	Endometrial cancer
Koselugo	Selumetinib	Neurofibromatosis type 1 (NF 1), plexiform neurofibromas
Minjuvi	Tafasitamab	Large B-cell lymphoma (DLBCL)
Opdualag	Nivolumab, relatlimab	Melanoma
Rybrevant	Amivantamab	Non-small cell lung cancer (NSCLC)
Scemblix	Asciminib	Chronic myeloid leukaemia (CML)
Tecvayli	Teclistamab	Multiple myeloma

Infectious diseases and vaccines

Medicinal product	Active substance(s)	Anwendung
Evusheld	Tixagevimab, cilgavimab	Pre-exposure prophylaxis and treatment of COVID-19
Fluenz Tetra	Live, attenuated influenza virus of the strains A/H1N1, A/H3N2, B/Yamagata, B/Victoria	Active immunisation for the prevention of influenza
MenQuadfi	Polysaccharides of Neisseria meningitidis groups A, C, W-135, Y	Active immunisation to prevent invasive meningococcal disease
Nuvaxovid	Spike protein of SARS CoV-2	Active immunisation to prevent COVID-19
Paxlovid	PF-07321332, ritonavir	Treatment of COVID-19
Regkirona	Regdanvimab	Treatment of COVID-19
Tenkasi	Oritavancin	Bacterial skin and skin structure infections
Xevudy	Sotrovimab	Treatment of COVID-19

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Dermatology and allergology

Medicinal product	Active substance(s)	Indication
Adtralza	Tralokinumab	Atopic dermatitis
Bimzelx	Bimekizumab	Plaque psoriasis
Cibinqo	Abrocitinib	Atopic dermatitis
Klisyri	Tirbanibulin	Actinic keratosis
NexoBrid	Concentrate of proteolytic enzymes enriched in bromelain	Skin burns

Endocrinology and metabolism

Medicinal product	Active substance(s)	Indication
Colibiogen oral	*Escherichia coli lysate* (strain Laves)	Irritable bowel syndrome
Lamzede	Velmanase alfa	Alpha-mannosidosis
Mounjaro	Tirzepatide	Type 2 diabetes mellitus
Ngenla	Somatrogon	Growth hormone deficiency
Nityr	Nitisinone	Tyrosinaemia type 1 (HT-1)

Immunology

Medicinal product	Active substance(s)	Indication
Idefirix	Imlifidase	Desensitisation treatment before kidney transplantation
Saphnelo	Anifrolumab	Systemic lupus erythematosus (SLE)
Tavneos	Avacopan	ANCA-associated vasculitis
Orladeyo	Berotralstat	Hereditary angioedema (HAE)

Neurology and psychiatry

Medicinal product	Active substance(s)	Indication
Ontozry	Cenobamate	Epilepsy
Quviviq	Daridorexant	Sleeping disorders (insomnia)
Sunosi	Solriamfetol	Narcolepsy, obstructive sleep apnoea (OSA)
Kapruvia	Difelikefalin	Pruritus associated with chronic kidney disease

Pulmonology

Medicinal product	Active substance(s)	Indication
Lyfnua	Gefapixant	Chronic cough
Solmucol Bronchoprotect	Lyophilised bacterial lysate	Prevention of recurrent respiratory tract infections
Tezspire	Tezepelumab	Asthma

Cardiology

Medicinal product	Active substance(s)	Indication
Rapibloc	Landiolol	Supraventricular tachycardia, sinus tachycardia
Vazkepa	Icosapent ethyl	Reduction of the risk of cardiovascular events

Urology and sexual medicine

Medicinal product	Active substance(s)	Indication
Drovelis	Drospirenone, estetrol	Oral contraception
Softigyn	*Lactobacillus plantarum*	Protection of the vaginal flora

Ophthalmology

Medicinal product	Active substance(s)	Indication
Vabysmo	Faricimab	Wet age-related macular degeneration (AMD), diabetic macular oedema (DMO)

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Authorisation of additional indications

Authorisation procedures	2020	2021	2022
Procedures with standard time limits			
Standard procedure	49	58	46
Reliance procedures*	2	10	3
Fast-track procedures			
Fast-track authorisation procedure	5	2	2
Procedure with prior notification	11	7	4
Access	0	0	1
Orbis	4	7	8
Total	**71**	**84**	**64**

*«Reliance procedures» combines all authorisations according to Art. 13 TPA and Art. 14 para. 1 let. a$^{bis-quater}$ TPA.

64 additional indications authorised

In 2022, Swissmedic authorised 64 additional indications The median turnaround time for the 64 applications, pooled across all procedures, was 345 CD (2021: 348 CD). 77% (n=49) of the applications were authorised in procedures with standard time limits and 23% (n=15) in accelerated procedures (fast-track authorisation procedure FTP, procedure with prior notification PPN or the international procedures Access and Orbis).

Procedure with standard time limits

- 72% (n=46) of the additional indications (2021: 77%) were processed in the standard procedure. The median turnaround time was 360 CD (2021: 378 CD).
- The reliance procedures according to Art 13 TPA were employed in 5% of cases (n=3). The median turnaround time was 237 CD (2021: 332 CD).

Fast-track procedures

- The FTP was used in 3% of cases (n=2). The median turnaround time was 302 CD (2021: 214 CD).
- The PPN, with a 20% shorter review time by Swissmedic, was applied in 6% of cases (n=4). The median completion time for additional indications in the PPN in 2022 was 313 CD (2021: 302 CD).
- 14% (n=9) of the additional indications (2021: 7%) were authorised in connection with international procedures:

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- 1 additional indication (2021: 0) was authorised in the work-sharing procedure of the Access Consortium. The turnaround time for this application was 340 days.

- Eight additional indications (2021: 7) for oncology medicines were authorised in Project Orbis during the financial year. The median turnaround time for the Orbis applications was 259 CD (2021: 216 CD).

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