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Authorisation of human medicinal products with new active substances and of additional indications

2020

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Authorisation of human medicinal products with new active substances

Authorisation procedure	2019	2020
Standard procedure	20	18
Fast-track authorisation procedure	2	7
Procedure with prior notification	4	5
Procedure for temporary authorisation	0	7
Simplified authorisation procedures	3	5
Totale	**29**	**42**

In 2020, Swissmedic authorised 42 human medicinal products with new active substances.

The median turnaround time for the applications, pooled across all procedures, was 482 calendar days.

- The fast-track authorisation procedure was used in 17% of cases. The median turnaround time for applications with this procedure was 280 calendar days.

- Nel 12% dei casi è stata applicata la procedura con notificazione preventiva, riducendo i tempi di valutazione di Swissmedic del 20%. Il valore mediano dei tempi di elaborazione con questa procedura è stato di 374 giorni civili.

- For the first time, temporary authorisations also accounted for a significant proportion of NA NAS (17%): temporary authorisation was requested by applicants for two medicinal products, which were thus reviewed within a shorter time. Five were authorised temporarily by Swissmedic on an „ex officio" basis.

- During the financial year, an innovative medicinal product was authorised for the first time in connection with the Orbis pilot project.[1] Another medicinal product was reviewed and authorised in the work-sharing procedure of the Access Consortium.[2]

[1] Orbis pilot project
www.swissmedic.ch/orbis-en

[2] Access Consortium
www.swissmedic.ch/access-consortium-en

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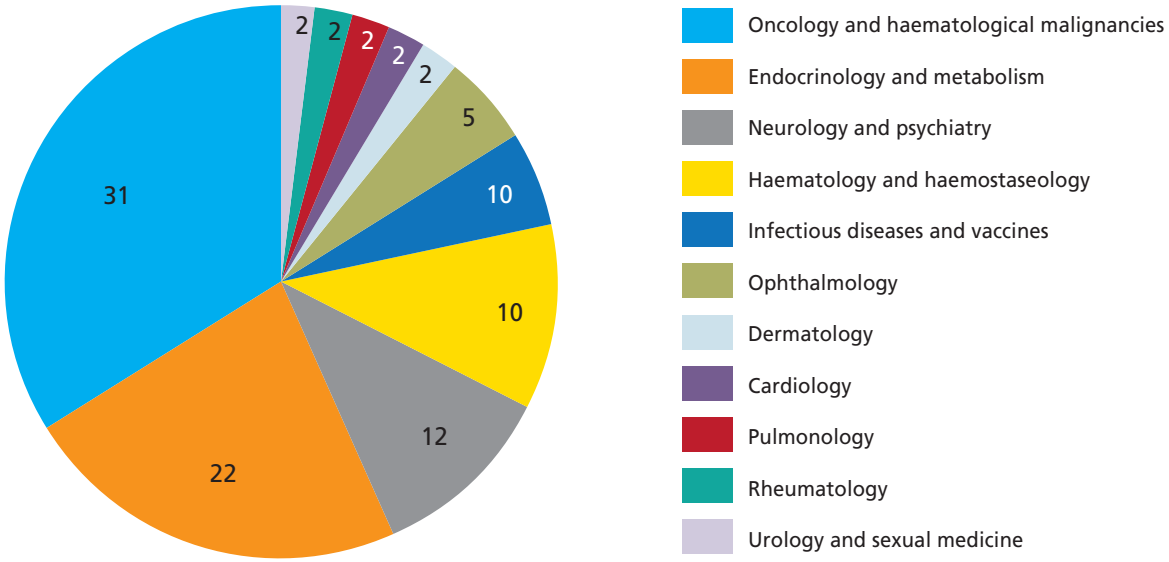
Authorised medicinal products according to indication

Graphic

Authorised medicinal products according to indication in %



Oncology and haematological malignancies again formed the largest group, accounting for 31% of authorised medicinal products. This continues the trend of previous years.

Medicinal product	Indication

Endocrinology and metabolism

Carbaglu	Hyperammonaemia
Cerdelga	Type 1 Gaucher disease
Pheburane	Disorders of urea cycle metabolism
Rybelsus	Type 2 diabetes mellitus
Triogen	Wilson's disease
Crysvita	X-linked hypophosphataemia (XLH)
Nilemdo	Hypercholesterolaemia
Isturisa	Hypercortisolism
Evenity	Osteoporosis

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Medicinal product	Indication
Haematology and haemostaseology	
Defitelio	Hepatic veno-occlusive disease (VOD)
Ultomiris	Paroxysmal nocturnal haemoglobinuria (PNH)
Mirasol	Pathogen inactivation procedure for blood
Ondexxya	Antidote against factor Xa inhibitors
Cardiology	
Vyndaqel	Transthyretin (TTR) amyloidosis
Dermatology	
Aklief	Acne
Urology and sexual medicine	
Mictonorm	Urinary incontinence, overactive bladder
Infettivologia e vaccini	
Comirnaty	Prevention of corona virus disease 2019 (COVID-19)
Quofenix	Skin and skin structure infections
Xofluza	Treatment of influenza
Veklury	Corona virus disease 2019 (COVID-19)
Pulmonology	
Trikafta	Cystic fibrosis

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Medicinal Product	Indication
Oncology and haematological malignancies	
Besremi	Polycythaemia vera
Libtayo	Cutaneous squamous cell carcinoma
Lorviqua	Lung cancer
Nerlynx	Breast cancer
Nubeqa	Prostate cancer
Piqray	Breast cancer
Rozlytrek	Solid tumours
Rubraca	Ovarian, fallopian tube and primary peritoneal cancer
Sarclisa	Multiple myeloma
Trecondi	Conditioning treatment prior to allogeneic haemato-poietic stem cell transplantation
Tukysa	Breast cancer
Vitrakvi	Solid tumours
Xospata	Acute myeloid leukaemia
Rheumatology	
Rinvoq	Rheumatoid arthritis
Neurology and psychiatry	
Spravato	Depression
Zebinix	Epilepsy
Zeposia	Multiple sclerosis
Enspryng	Neuromyelitis optica spectrum disorder (NMOSD)
Mayzent	Multiple sclerosis
Ophthalmology	
Beovu	Age-related macular degeneration (AMD)
Luxturna	Vision loss due to inherited retinal dystrophy

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Authorisation of additional indications

Authorisation procedure	2019	2020
Standard procedure	57	51
Fast-track authorisation procedure	7	5
Procedure with prior notification	10	13
Simplified authorisation procedures	5	2
Total	**79**	**71**

In 2020, Swissmedic authorised 71 additional indications.

The median turnaround time for the applications, pooled across all procedures, was 339 calendar days.

- The fast-track authorisation procedure was used in 7% of cases. The median turnaround time was 225 calendar days.
- The procedure with prior notification (PPN), with a 20% faster review time by Swissmedic, was applied in 18% of cases. The median completion time for AI in the PPN in 2020 was just 290 calendar days.
- During the financial year, five additional indications were authorised for the first time in connection with the Orbis pilot project.[1]

[1] Orbis pilot project
www.swissmedic.ch/orbis-en

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